ENROLLMENT AND MEDICAL ORDER FORM

Send completed form by **fax (1-855-788-3140)** or **email (Benlysta-Monarch@supportprogram.com)**

PLEASE DO NOT SEND THIS FORM TO GSK

PATIENT INFORMATION		
First name:		
Last name:		
Date of birth (dd/mm/yyyy): / /	Sex: ☐ M ☐ F ☐ Other	
Address:		
City:	Province:	Postal code:
Primary phone:	May we leave a message? ☐ Yes ☐ No	
Alternate phone:	May we leave a message? ☐ Yes ☐ No	
Email:		
Language preference: ☐ English ☐ French ☐ Other, please specify:		
Allergies:		

PHYSICIAN INFORMATION		
First name:		
Last name:		
Address:		
City:	Province:	Postal code:
Phone:		
Fax:		
Email:		
If further information is required, who should we contact? Name: Phone: Email:		

INFORMATION REQUIRED FOR REIMBURSEMENT

THERAPY HISTORY (indicate all that apply, this information may facilitate reimbursement process with patient insurance)

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

SELENA-SLEDAI score:

BENLYSTA R_x

Start BENLYSTA once coverage is secured: ☐ YES ☐ NO

Fill in the sections below for SUBCUTANEOUS (SC) injection:	Fill in the sections below for INTRAVENOUS (IV) infusion:
☐ BENLYSTA for subcutaneous (SC) injection with the autoinjector for patients with **SLE**. Dose 200 mg once weekly.	☐ BENLYSTA for IV infusion (dose 10 mg/kg) for patients with SLE and/or lupus nephritis. **Frequency of administration:** ☐ **Initial order:** Weeks 0, 2, and 4, then every 4 weeks
Duration of order (weeks): ☐ 26 ☐ 52 ☐ See R_x attached ☐ Other:	**Weight:** _____ kg **Dose:** Give _____ mg Infuse over at least 1 hour as per BENLYSTA Product Monograph.
OR	
☐ 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.	**Pre-treatment orders:** 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:	**Duration of order** (weeks): ☐ 26 ☐ 52 ☐ See R_x attached ☐ Other:

PHYSICIAN AUTHORIZATION

I hereby certify that (i) I am prescribing BENLYSTA for this patient in accordance with its intended use as outlined in the Product Monograph (available at www.gsk.ca):

BENLYSTA is indicated in addition to standard therapy for reducing disease activity in adult patients with active, autoantibody-positive, systemic lupus erythematosus (SLE) and adult patients with active lupus nephritis. The safety and efficacy of BENLYSTA have not been evaluated in patients with severe active central nervous system lupus. The efficacy of BENLYSTA in patients of Black African heritage has not been clearly established.

(ii) the above prescription constitutes an original BENLYSTA prescription for this patient; and (iii) subject to the above noted patient's consent. I agree to be contacted by GSK and its affiliates and their respective employees, consultants, agents, and representatives, including without limitation, third-party service providers, in connection with the patient's enrollment in the BENLYSTA Monarch Program.

Physician signature:

License number: **Date** (dd/mm/yyyy): / /

PATIENT CONSENT (select only one form of consent)

☐ I have read, understood, and agreed to the Patient Consent statement below.

Patient signature:

Email:

Date (dd/mm/yyyy): / /

☐ **Verbal consent provided on** (dd/mm/yyyy): / /

BENLYSTA Monarch Program
Consent Information and Patient Disclosure

BENLYSTA Monarch Program ("Program") is designed to facilitate access and provide further information and assistance to qualifying patients that have been prescribed BENLYSTA. I understand the services under the Program include: (1) reimbursement and financial support (such as investigating your insurance coverage, confirming out-of-pocket costs, and reviewing eligibility for financial assistance); (2) arranging for dispensing and administration of BENLYSTA at a clinic, including nursing and administration support; and (3) disease and medication resources and communications.

Who administers the Program?

The Program is a GlaxoSmithKline Inc. ("GSK") program and is administered by a third-party service provider, selected from time to time by GSK ("Service Provider"). I understand GSK reserves the right to appoint other third-party service providers to administer the Program, in addition or in replacement of the current provider, and I consent to my information being transferred to any future Service Provider involved in the administration of the Program.

GSK does not, in the normal course, access Your Information (defined below) 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). The Service Provider may provide GSK with de-identified or aggregate information collected in the course of the Program, which may be used by GSK for clinical research, market research, or internal evaluation purposes, and disclosed by GSK to third parties in accordance with GSK's Privacy Notice available at https://privacy.gsk.com/en-ca/privacy-notice/general.

What Personal Information is collected?

By signing this authorization ("Authorization"), I hereby consent to enroll in the Program and to the collection, use, and disclosure of My Information for the services provided under the Program described above. I acknowledge that in order to enroll in the Program, and to continue my participation in the Program once enrolled, Service Provider, on behalf of GSK, may collect and store (i) personal information, including the information provided on the enrollment form ("Personal Information"); (ii) medical information as it relates to my medical condition for which BENLYSTA has been prescribed ("Medical Information"); and (iii) financial information ("Financial Information"). Personal Information, Medical Information, and Financial Information (collectively, "My Information" or "Your Information") will be collected by Service Provider on behalf of GSK, from me, my caregivers, my physician, my pharmacist, and other healthcare professionals involved in my care, as set out below.

My Information may also be collected by a clinic associated with the Program, for the administration of BENLYSTA ("Clinic"), if I so choose to receive the administration of BENLYSTA at such Clinic. My Personal and Medical Information shall be collected by the Clinic and used solely for purposes related to my participation in the Program and may be shared with Service Provider and GSK for Program administration, and with other healthcare professionals involved in my care, only in accordance with the permitted disclosures described in this form.

I authorize Service Provider, on behalf of GSK, to contact as well as to collect further information from my prescribing physician, pharmacist, nurse, other healthcare professionals involved in my care, insurer, government agency, or employer, as deemed necessary to ensure the accuracy and completeness of this application and to administer the Program.

How is Personal Information used?

My Financial Information shall be collected solely for the purposes of verifying and arranging for insurance coverage (including with third-party insurance providers) or to assist me in obtaining financial assistance. I acknowledge that I may be contacted as part of any audit, as may be required, to verify that any Financial Information collected from me is accurate and that my participation in the Program is valid. I confirm that the Financial Information I provide to the Program will be complete and accurate.

How is Personal Information stored, and who can you contact for questions?

My Information will be stored in a secure and confidential database, with access to the database 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 understand that to request access or to make inquiries or complaints, I can contact the Program by fax (1-855-788-3140) or email (Benlysta-Monarch@supportprogram.com).

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) GSK may cancel or revise the Program at any time; (v) I may revoke this Authorization at any time by sending a signed letter of revocation to Fax: 1-855-788-3140 or Mail: BENLYSTA Monarch Program, 70 Wynford Drive, PO Box 383, North York ON, M3C 2S7, but, if I do so, I will no longer be able to participate in the Program; (vi) 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; and (vii) unless and until revoked, this Authorization is valid for as long as I am enrolled in the Program or for one full year from the date signed, whichever is longer in duration. I understand that My Information may be stored 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 to the above, 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.

Consult the Product Monograph at http://ca.gsk.com/media/600543/benlysta.pdf for contraindications, warnings, precautions, adverse reactions, interactions, dosing and conditions of clinical use.
The Product Monograph is also available through our medical department. Call us at 1-800-387-7374.

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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MEMBER OF INNOVATIVE MEDICINES CANADA

REVIEWED BY PAAB

Benlysta (belimumab)

The Benlysta monarchprogram

gsk