Bristol Myers Squibb®
Patient Support Program >
Your patient. Our commitment.

ENROLMENT FORM

Pr Reblozyl®
luspatercept for injection

FAX THIS COMPLETED FORM TO 1-833-951-2483; TO SPEAK WITH A PROGRAM REPRESENTATIVE, CALL 1-833-951-2482 (TOLL FREE), MONDAY TO FRIDAY (8 A.M. – 8 P.M. ET)

Fields denoted by an asterisk (*) are mandatory.

Section 1: Patient Information

Last name*: | First name*:

Health Card Number: | Date of birth (DD/MM/YYYY)*: | Gender: ☐ Male ☐ Female

Address*: | City/Province*: | Postal code*:

Primary telephone number*: | Secondary telephone number: | Email:

Preferred method of contact: ☐ Phone ☐ Email | Best time to contact: ☐ Morning ☐ Afternoon ☐ Evening ☐ Do not leave message

Alternate contact name: | Alternate telephone number:

Third-party coverage*

☐ Speak to the patient for complete details of his/her insurance program

☐ This patient has the following third-party private insurance coverage:

	Insurer	Name of plan participant	Policy #	Certificate #	Has prior authorization form been sent?
Principal insurance plan					☐ Yes ☐ No
Secondary insurance plan					☐ Yes ☐ No

Section 2: Prescribing Physician Information

Last name*: | First name*:

Address*: | City/Province*: | Postal code*:

Telephone number*: | Fax number*: | Email: | Preferred method of contact: ☐ Phone ☐ Email ☐ Fax

Primary contact name (if different from the prescribing physician):

Telephone number*: | Fax number: | Email: | Preferred method of contact: ☐ Phone ☐ Email ☐ Fax

Section 3: Clinical Information and Prescription*

REBLOZYL (luspatercept) is available in 2 vial strengths (25 mg and 75 mg)

☐ Adult patient with transfusion-dependent anemia due to very low- to intermediate-risk myelodysplastic syndromes (MDS) who have not been previously treated with an erythropoiesis stimulating agent (ESA-naïve).

☐ Adult patient with transfusion-dependent anemia requiring at least two RBC units over 8 weeks resulting from very low- to intermediate-risk MDS who has ring sideroblasts (RS+) and who has failed or is not suitable for erythropoietin-based therapy.

Transfusion-dependent anemia requiring RBC units of
☐ 2-3 units within 8 weeks ☐ 4-5 units within 8 weeks ☐ ≥ 6 units within 8 weeks

RS percentage
☐ RS- ☐ ≥ 5% with *SF3B1* mutation ☐ ≥ 15%

IPSS-R prognostic risk score
☐ Very low-risk (≤ 1.5) ☐ Low-risk (> 1.5 – 3) ☐ Intermediate-risk (> 3 – 4.5)

ESA treatment history
☐ Naïve ☐ Failed prior erythropoietin-based therapy ☐ Not suitable for erythropoietin-based therapy

Dosage strength requested

Recommended starting dose†:
☐ 1.0 mg/kg every 3 weeks by SC injection

Dose valid for a maximum of 8 dosing cycles

Otherwise, please specify:

Targeted therapy start date: _____

Patient weight: _____ kg

Date weight taken (DD/MONTH/YYYY): _____

The Authorization to Inject (ATI) form is used when your patient is receiving their REBLOZYL injections. The Program will send you this form at your convenience. Please indicate your preference:

☐ **OPTION 1:** Send me **ONLY ONE** ATI form to complete every 8 cycles.

☐ **OPTION 2:** Send me an ATI form to complete **BEFORE EACH INJECTION**.

Preferred injection clinic* ☐ PSP-affiliated clinic ☐ Prescriber clinic, please specify:

Monitor blood pressure and assess and review hemoglobin (Hgb) results prior to each administration. If an RBC transfusion occurred prior to dosing, the pre-transfusion Hgb must be considered for dosing purposes. Please see the Product Monograph for complete dosing recommendations.

By signing below, I acknowledge that I am responsible for informing the Patient Support Program for REBLOZYL of any changes to the prescribed REBLOZYL dosing regimen appropriate for this patient after reviewing and assessing the patient's blood tests prior to each injection. In the absence of any reported changes from Physician to Program, such as adjusting the patient dose or discontinuing treatment based on how the patient responds to REBLOZYL, the Program should continue to dose the patient in accordance with my most recent instructions.

I certify that I am the prescribing physician

☐ I confirm I have received the following REBLOZYL Risk Minimization tools to support my patient during treatment‡: Prescriber's Checklist and Patient Card.*

Signature*: | Date (DD/MONTH/YYYY)*:

Physician license number*:

ESA: erythropoiesis-stimulating agent; IPSS-R: International Prognostic Scoring System, revised; RBC: red blood cell; RS-: ring sideroblast–negative; SC: subcutaneous.

† If there is an increase in Hgb > 20 g/L within 3 weeks of the previous dose, and in the absence of transfusion, reduce dose as per the dosage adjustment recommendations from the Product Monograph.

‡ Copies of the REBLOZYL Risk Minimization tools can be obtained by contacting Bristol Myers Squibb Canada Medical Information by phone (1-866-463-6267) or by email (medical.canada@bms.com).

Section 4: Patient Consent*

PROGRAM ENROLMENT AND **PATIENT PRIVACY CONSENT**

The **Patient Support Program for REBLOZYL** (which we will refer to as the "**Program**") is a customer service program that provides patients like you (we will refer to as "**you**" or "**your**") who have been prescribed REBLOZYL with educational and therapy support services. Your personal information may be collected, used, or disclosed for Program purposes outlined above and for related purposes outlined in the *Use and disclosure of your personal information* section in SCHEDULE A. **This consent is required to have access to the services being provided by the Patient Support Program for REBLOZYL**.

PLEASE ENSURE YOU HAVE READ AND FULLY UNDERSTAND THE TERMS OF THE AGREEMENT IN **SCHEDULE A**.

I consent to enrol in the Patient Support Program for REBLOZYL and to the conditions set forth in the Patient Privacy Consent Form.

Signature of patient or legal representative*: _____

Date (DD/MONTH/YYYY)*: _____

☐ Check box where consent provided through substitute decision maker
(print name of substitute decision maker):

Last name: _____

First name: _____

☐ By checking this box, I authorize the Administrator to communicate with me through email for purposes related to the Patient Support Program for REBLOZYL. I understand that email may not be the most secure means of communication and as such, the Administrator will not include sensitive health information in any emails used to communicate with me. Such emails may, however, identify me as an individual registered with the Program. I may withdraw my consent to receive emails by contacting the Administrator.

COLLECTION AND USE OF INFORMATION FOR MARKET RESEARCH OR HEALTH OUTCOMES RESEARCH **(OPTIONAL)**

From time to time, the Administrator or BMS, as applicable, may (i) retain the services of third-party market research firms to better understand the patient experience of individuals enrolled in the Program or make improvements to the Program ("**Market Research**") or (ii) conduct Health Outcomes Research to provide information for insurers, public health plans, regulators and other interested stakeholders for products like REBLOZYL® ("**Health Outcomes Research**"). At such time, the Administrator may reach out to you to provide consent to participate in such Market Research or Health Outcomes Research, as applicable. Participation in any Market Research or Health Outcomes Research is voluntary and the patient may withdraw consent at any time by notifying the Administrator using the information outlined in the Administrator Contact Information section below.

Your consent to participate in any Market Research or Health Outcomes Research is not required in order to have access to the services being provided by the Program.

VERBAL PATIENT CONSENT *(when written consent is not possible)*

If a healthcare provider is unable to obtain written consent from patient, please document when patient verbal consent was obtained. This will allow the Program to continue with processing this document.

The patient has given consent to:

☐ **Program Enrolment and Patient Privacy Consent (required to enrol in the program)**

☐ By checking this box, I authorize the Administrator to communicate with me through email for purposes related to the Patient Support Program for REBLOZYL. I understand that email may not be the most secure means of communication and as such, the Administrator will not include sensitive health information in any emails used to communicate with me. Such emails may, however, identify me as an individual registered with the Program. I may withdraw my consent to receive emails by contacting the Administrator.

Verbal consent obtained by healthcare provider

Signature: _____

Date (DD/MONTH/YYYY): _____

Last name: _____ First name: _____

Section 5: Agreement and Consent to Disclose Health Information

SCHEDULE A
PROGRAM ENROLMENT AND PATIENT PRIVACY CONSENT
BY SIGNING THIS FORM, YOU ACKNOWLEDGE THAT YOUR PERSONAL INFORMATION WILL BE COLLECTED, USED, AND/OR SHARED FOR THE PURPOSES OUTLINED BELOW.

About the Patient Support Program for REBLOZYL

The **Patient Support Program for REBLOZYL** (which we will refer to as the "**Program**") is a customer service program that provides patients like you (we will refer to as "**you**" or "**your**") who have been prescribed REBLOZYL with educational and therapy support services, including:

- Education about the REBLOZYL treatment;
- Therapy administration services such as coordinating delivery of REBLOZYL to you and assistance with the administration of REBLOZYL (collectively we will refer to them as the "**Support Services**").

Your personal information may be collected, used, or disclosed for Program purposes outlined above and for related purposes outlined in the *Use and disclosure of your personal information* section below.

Who is running this Program?

The Program is sponsored by Celgene Inc., a Bristol Myers Squibb Company ("**BMS**") and is administered on behalf of BMS by Bayshore HealthCare Ltd, a third-party company that provides client-focused services and patient support program services (we will refer to Bayshore HealthCare Ltd as the "**Administrator**"). If Bayshore HealthCare Ltd ceases to be the Administrator, BMS may appoint a replacement administrator to administer the Program. In such a circumstance, your personal information will be transferred to and used by the replacement Administrator in the manner described on this form, to continue to administer the Program and provide you with Support Services.

Collection of your personal information

The Administrator may collect your personal information directly from you and your authorized representatives (e.g., a substitute decision maker), doctors, nurses, pharmacists, private insurance companies, public payers and any other healthcare provider or payer that may possess the necessary information. Generally, "personal information" refers to:

- Your name, address, phone number, email address, date of birth;
- Details of your medical conditions, medical history, medical treatments, and drug prescription information; and
- Financial information such as your insurance coverage.

The Administrator will only collect the minimum amount of personal information necessary to administer the Program or provide you with the Support Services.

Use and disclosure of your personal information

The Administrator (and its authorized representatives and agents) may collect, use and/or share your personal information to:

- Administer the Program;
- Provide you with the Support Services;
- Determine your eligibility for the Program and Support Services;
- Personalize the Program and Support Services to your specific circumstances;
- Provide you with materials relating to your medication, treatment, and the Program;
- Contact you to inform you of changes in the Program and Support Services;
- Obtain your feedback on the Program and Support Services;
- Evaluate and report patient outcome data associated with the administration of REBLOZYL;
- Perform internal evaluation and assessments of the Program and Support Services; and
- Undertake safety monitoring, reporting, and auditing and responding to enquiries or issues in relation to medication, or as otherwise may be required by law.

The Administrator may also share your personal information with other health professionals in your circle of care (e.g., your doctor, pharmacist) and your public/private health insurance provider to: enroll you into the Program; administer the Program; provide you with the Support Services; provide you with materials in relation to your medication, treatment, medical condition, or other health-related reasons; or as otherwise may be required for legal or regulatory purposes.

BMS's access or use of your information

The Administrator, in the normal course of administering the Program, will not directly share your personal information with BMS or its service providers; however, the Administrator may share your personal information with BMS or its service providers in limited circumstances, including:

- For safety monitoring and regulatory reporting purposes (e.g., reporting an adverse reaction to Health Canada);
- To transfer your personal information to a new Program administrator; or
- To perform audits of the Program in order to evaluate or improve the Program.

Additionally, BMS may transfer any personal information related to the Program in connection with the sale or transfer of all or a portion of its business or assets or rights in those businesses or assets. Should such a sale or transfer occur, BMS will request that the purchaser use and disclose personal information you have provided through this Program in a manner that is consistent with the purposes disclosed here.

The Administrator may share with BMS de-identified or aggregate data generated from information collected in the course of the Program, which may then be used by BMS for the purposes of:

- Developing, evaluating, or improving the Program and Support Services (including patient participation and experiences) or the REBLOZYL treatment approaches and implementation;
- Financial administration of the Program or Support Services; or
- Conducting clinical research, including future scientific research, regulatory submissions, and publications.

Protection of your personal information

BMS is legally responsible for protecting any personal information collected from you in connection with the Program in accordance with applicable privacy laws. A copy of the BMS Privacy Policy is available at: **https://www.bms.com/ca/en/privacy-policy.html**.

Storage of your personal information

The Administrator and/or BMS may transfer, store, or process personal information outside Canada. In such circumstances your personal information may be subject to the laws of the foreign country where it is stored, and those other foreign countries may have a different level of legal protection than your country of residence. As a result, in certain circumstances, other foreign governments, courts, law enforcement agencies, or regulatory agencies may be entitled to access or collect personal information.

Your personal information will be kept for the duration of your participation in the Program and will thereafter be deleted in accordance with the Administrator's and BMS's document retention policies, subject to legal and regulatory requirements.

Access or correction of your personal information

You may request access to and/or correction of your personal information held by the Administrator by contacting them using the information outlined in the *Administrator Contact Information* section.

Withdrawal from the Program or withdrawal of consent

Your participation in the Program is voluntary. If you choose not to participate, neither your medical treatment nor your insurance coverage eligibility will be impacted. You may refuse to sign the consent form and/or refuse to consent to the collection, use and disclosure of your personal information, as outlined above. However, if you do not consent to the collection, use and disclosure of your personal information as described in this form, you will not be able to participate in the Program or receive Support Services.

You may cancel your enrolment or revoke your consent at any time by sending a written and signed request to the Administrator using the information outlined in the *Administrator Contact Information* section. Your cancellation will take effect upon receipt of the letter by the Administrator. In such situations, no new personal information will be collected from you, but your personal information will be maintained as required for legal and regulatory purposes, and BMS may continue to use de-identified or aggregated information as described above.

Administrator Contact Information

If you wish to make inquiries or complaints or have other concerns about the collection, use or information of your personal information as part of Program or Support Services, about Administrator's personal information practices, to withdraw your consent, or to request access or correction to your personal information you may contact the Administrator in writing using the following contact information:

Mailing address: 2101 Hadwen Rd, Mississauga, ON L5K 2L3
Fax (toll free): 1-833-951-2483 **Phone (toll free):** 1-833-951-2482

The Administrator may need to confirm your identity or request additional details in order to process your request.

BY SIGNING THIS CONSENT FORM:

- I confirm that I have read, fully understand, and consent to the collection, use, and disclosure of my personal information in accordance with the terms outlined in this Patient Privacy Consent Form.
- I understand that I am not required to sign this consent form. If I choose not to consent to the collection, use, and disclosure of my personal information, I will not be able to participate in the Program.
- I understand that participation in the Program is not required for me to have access to REBLOZYL.
- I give permission for my healthcare professionals, pharmacies, health insurance providers, or payers to share my personal information, including information about prescriptions, medical condition, health, and financial information, with the Administrator or its agents, so that the Administrator may use the personal information to provide the Support Services and administer the Program as described above.
- I understand that telephone calls between me and employees of the Administrator may be monitored or recorded for quality control or training purposes.
- I recognize that my personal information may be transferred and stored outside of Canada.
- I understand that all the information provided to BMS may be shared with its group companies for the purposes outlined in *BMS's access or use of your information* section.
- I understand that BMS may share my personal information with regulatory authorities such as Health Canada or other government agencies in and outside of Canada in the context of reporting any adverse drug events or as otherwise required by law.
- I acknowledge that unless and until revoked, my consent is valid for the duration of my participation in the Program. I accept that even after I withdraw my consent or after stop participating in the Program my personal information will be maintained as required for legal and regulatory purposes, and BMS may continue to use de-identified or aggregated information as described *BMS's access or use of your information* section.
- I accept that BMS reserves the right to modify, suspend, or terminate the Program or any or all Support Service, or any part thereof, in its sole discretion, including changing third-party service providers. BMS will provide me notice of such changes where required by law.

For more information:

Consult the REBLOZYL Product Monograph for important information relating to contraindications, warnings, precautions, adverse reactions, interactions, dosing, and conditions of clinical use.
The Product Monograph is also available by calling our medical information department at: **1-866-463-6267**.

CLEAR FORM

Bristol Myers Squibb®

MEMBER OF INNOVATIVE MEDICINES CANADA

Pr Reblozyl® luspatercept for injection

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