PrLEQVIO® inclisiran injection

Leqvio ASSIST Patient Support Program

PrLEQVIO® Assist Patient Support Program Enrolment Form

t: 1-833-928-4055 | e: leqvio.assist@novartis.com | f: 1-833-644-9681

NOVARTIS

PATIENT INFORMATION AND CONSENT

Sticker can be applied where information is present

Last name | First name

YYYY-MM-DD | Sex: ☐ M ☐ F

Date of birth

Home address | Unit #

City | Province | Postal code

Email address

Cell: ☐ **Yes** ☐ **No**

Primary # | Alternate #

Best time to contact: ☐ AM ☐ PM ☐ Evening ☐ Cannot leave a message

Preferred communication language: ☐ English ☐ French ☐ Other:

Printed name of legal guardian (if applicable)

Relationship to the patient

Contact #

Primary care provider name

A LEQVIO® Assist enrolment notification may be sent to primary care provider.

Does the patient have private health insurance coverage? ☐ **Yes** ☐ **No**

If no coverage, will the patient cover the costs of prescription? ☐ **Yes** ☐ **No**

Injection service options: ☐ **PSP to coordinate** ☐ **Physician's office**

Patient has received the 1st dose: ☐ **Yes** ☐ **No** Date: YYYY-MM-DD

I would like to be enrolled in the Novartis LEQVIO® Assist Patient Support Program. I have read and agree to the patient consent in Section A, page 2 of this document. The Program may wish to contact me via electronic means; I will have the opportunity to opt out from such communications.

☐ **I accept that representatives of the Program may contact me via electronic means such as email or text message, and that I am able to opt out of this service at any time.**

Patient's or Legal Representative's Printed Name

Patient's or Legal Representative's Signature | Date (YYYY-MM-DD)

PRESCRIBING PHYSICIAN'S INFORMATION

Check box below if patient is unable to sign patient consent (signed patient consent will be obtained at a later date):

☐ I, the prescriber, have received verbal consent from the patient to initiate the enrolment process.

Prescriber name | Specialty

Phone | Fax | Email

Office address

City | Province | Postal code

☐ **I, the prescriber, would like to receive a quarterly summary report on this patient.**

I wish to get the update status by: ☐ **Fax** ☐ **Email**

By providing the information above, I acknowledge that I have read and understand the information provided in the Prescriber Privacy Notice and consent to the collection, use, and disclosure of my personal information as detailed in said notice.

Office stamp/other information

LEQVIO® (INCLISIRAN INJECTION) PRESCRIPTION INFORMATION

Initial Rx ☐ LEQVIO® (inclisiran injection) 284 mg/1.5 mL pre-filled syringe injected subcutaneously at months 0, 3, and then every 6 months.
Quantity: 3 syringes for 12 months' (month 0, 3, and 9) supply.

Renewal Rx ☐ LEQVIO® (inclisiran injection) 284 mg/1.5 mL pre-filled syringe injected subcutaneously every 6 months.
Quantity: ____ syringes for ____ months' supply.

Note: LEQVIO® (inclisiran injection) is intended for administration by a health care professional (e.g., doctor, nurse, or pharmacist [where permitted]), according to the Dosing & Administration section of the LEQVIO® (inclisiran injection) Product Monograph.

PHYSICIAN CONSENT

I certify that this prescription order is an original prescription.
The designated pharmacy is the only recipient. The original will not be reused.

Physician signature

Physician license # | Date (YYYY-MM-DD)

MEDICAL INFORMATION

Patient Diagnosis

☐ **Non-familial hypercholesterolemia with atherosclerotic cardiovascular disease (ASCVD)**

☐ **Heterozygous Familial Hypercholesterolemia (HeFH)**

Criteria (please include information)

☐ **CCS Algorithm**
Ruel *et al.* Simplified Canadian Definition for FH.
***Canadian Journal of Cardiology*, 2018**

☐ **Dutch Lipid Network criteria**

☐ **Simon Broome**

☐ **Genetic testing**

Note: a patient must be prescribed a maximally-tolerated dose of a statin to be eligible for treatment with LEQVIO®.

ADDITIONAL CLINICAL INFORMATION

To further aid in the reimbursement process, please include the following relevant additional clinical information.

LDL-C

• Current LDL-C (≤3 months): ____ mmol/L • Date measured: YYYY-MM-DD

Current lipid-lowering treatments and doses

Treatment	Dose	
1. Statin:		Maximally tolerated by patient: ☐ Yes ☐ No
2. Ezetimibe: ☐ Yes ☐ No		
3. Other lipid-lowering therapies:		
4.		

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PATIENT CONSENT

What is the LEQVIO® Assist Patient Support Program?

The LEQVIO® Assist Patient Support Program (the "Program") is a patient support program provided by Novartis Pharmaceuticals Canada Inc. and/or its affiliates (collectively "Novartis", we, us, our) to provide Canadian patients who have been prescribed LEQVIO® (inclisiran injection) patient support services. Your health care professional believes you could benefit from the Program. The Program services may include health/disease/product information, insurance reimbursement assistance or treatment services (the "Services").

Novartis is the administrator of the Program (the "Administrator"); its employees and/or agents handle your Personal Information, which is processed in accordance with privacy laws and Novartis privacy/data protection standards. You will be notified should the Administrator change, your Personal Information will continue to be protected with equivalent safeguards.

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. However, if you do not participate, you cannot receive assistance or Services from the Program. The Program is not intended to provide medical advice or medical diagnoses. You agree to seek the advice of your physician or other qualified health care professional if you have health concerns, and not to disregard professional medical advice based on information obtained from the Program. Novartis reserves the right to modify or terminate the Program at any time without prior notice.

In the event that you elect to benefit from any external support referral service offered by the Program to help you locate available resources in your community, you understand that the third-parties to whom you may be referred by the Program are in no way affiliated with, or monitored by, Novartis. You understand that you are solely responsible for your interactions with these third-parties and Novartis cannot be held responsible for the information or services that these third-parties may offer to you.

Why is Personal Information collected, for which purposes and to whom could it be shared with?

Information, such as your date of birth, contact information, drug/medical, and insurance/financial information (collectively "Personal Information") is collected to communicate with you, provide you with the Program Services, audit or monitor the Program, and perform certain activities as required or permitted by law, including to process and report adverse events ("AEs"). We may contact you at the contact information you have provided; email, phone, or other (if via cellular, we will not assume any resulting cellular phone charges). Only relevant personnel will have access to your Personal Information.

Your Personal Information may be collected from and disclosed to health care professionals, insurance providers or other third-parties, as needed for the Program's administration and Services. Our third-parties providers are contractually obliged to strict data protection and security requirements.

In the case of AE processing and reporting to regulatory authorities, if monitoring or auditing is performed, or if required and/or permitted by law, it may be that Novartis employees or agents not assigned to the Program will have access to your Personal Information.

Your Personal Information may be de-identified (replace your identifying data with a code or label), aggregated (combined with other data), or anonymized to conduct analyses for commercial, research or publication purposes. Analyses are performed to help us improve our offers and services such as this Program, others, treatment reimbursement, disease educational campaigns, online communications and, may be conducted using digital capabilities.

Your Personal Information may be stored or processed outside of Canada, including for AEs processing and reporting requirements. In such cases, Novartis ensures that your Personal Information is protected. Your Personal Information may be subject to the laws of foreign jurisdictions, with a different level of protection than your country of residence.

What happens if I withdraw from the Program?

You may revoke your consent at any time. Withdrawing your consent will result in the termination of your participation in the Program and its Services; no new Personal Information will be collected, the file containing your Personal Information will be maintained during the term of the Program for monitoring and regulatory purposes, de-identified, aggregated, or anonymized data may continue to be used as described above.

You may request access or correction to your file by contacting the Novartis Privacy Officer at 385 Bouchard Blvd, Dorval, Quebec, H9S 1A9 or privacy.pharmacanada@novartis.com.

By signing the consent, you agree to the collection, use and disclosure of your Personal Information as described herein. You can learn more about how Novartis protects privacy at www.novartis.ca/en/privacy-policy.

Consent to contact via electronic communications

The Program may wish to contact you via electronic means; you will have the opportunity to opt-out from such communications.

☐ I accept that representatives of the Program may contact me via electronic means such as email, text message.

PHYSICIAN CONSENT

I have read the Patient Consent and (1) agree to my patient being enrolled in the LEQVIO® Assist Patient Support Program ("Program"); (2) have prescribed the drug specified on this form in accordance with its Product Monograph; and (3) have the patient's consent to share with the Program the patient's information in this form and as needed to provide the Program's services.

I accept that my information, including personal information, may be used by Novartis or its agents for reasons related to improving, monitoring, and auditing its programs, for commercial or market research purposes and as otherwise required or permitted by law. Details about how my file will be maintained, shared and how to access/correct my information, are as set out in the Patient Consent.

I acknowledge that adverse events may be reported about my patients participating in the Program and understand I may be contacted by Novartis or its agents to provide follow-up information. As adverse event reports may need to be processed in and outside of Canada and forwarded to Canadian and foreign regulatory authorities, I understand that my information may be stored or processed outside of Canada.

I have discussed the Program with the patient who wishes to enroll and has agreed that I share their personal information with the Program to contact patient and confirm enrolment.

LEQVIO® (inclisiran injection) is indicated as an adjunct to lifestyle changes, including diet, to further reduce low-density lipoprotein cholesterol (LDL-C) level in adults with the following conditions who are on a maximally tolerated dose of a statin, with or without other LDL-C-lowering therapies:

- Heterozygous familial hypercholesterolemia (HeFH), or
- Non-familial hypercholesterolemia with atherosclerotic cardiovascular disease

The effect of LEQVIO® (inclisiran injection) on cardiovascular morbidity and mortality has not been determined.

Consult the Product Monograph at https://www.novartis.ca/Leqviomonograph for contraindications, warnings, precautions, adverse reactions, interactions, dosing, and conditions of clinical use.
The Product Monograph is also available by calling 1-800-363-8883 or medinfo.canada@novartis.com.

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REVIEWED BY PAAB