



# The LEQVIO<sup>®</sup> Alternate Site of Care Referral Guide

This guide provides general guidance to help practices refer patients to an alternate site of care (ASOC) (eg, physician office, hospital outpatient department, independent injection/treatment center, etc).

If you have questions, reach out to your Novartis Access and Reimbursement Expert.

Name: \_\_\_\_\_ Phone: \_\_\_\_\_

Title: \_\_\_\_\_ Email: \_\_\_\_\_

# Indication & Important Safety Information

## INDICATION

LEQVIO<sup>®</sup> (inclisiran) injection is indicated as an adjunct to diet and statin therapy for the treatment of adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH), to reduce low-density lipoprotein cholesterol (LDL-C).

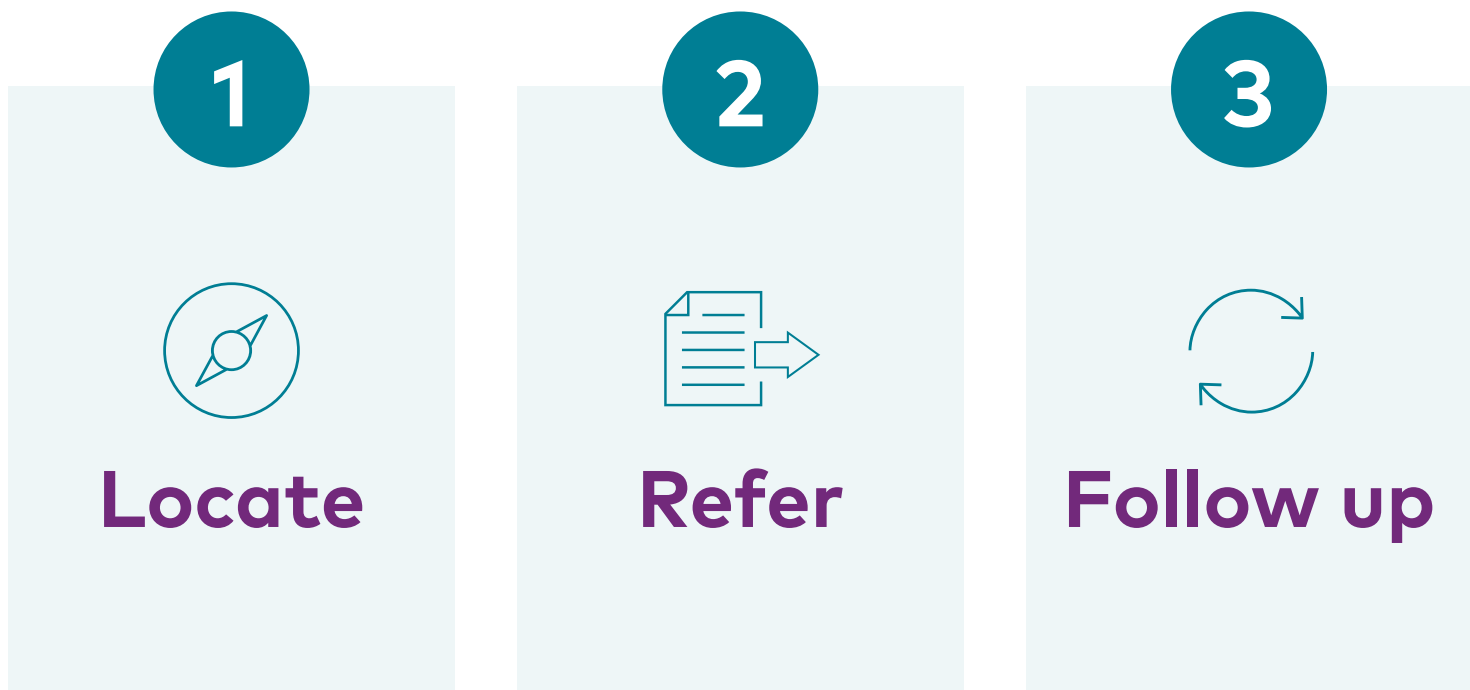
## IMPORTANT SAFETY INFORMATION

Adverse reactions in clinical trials ( $\geq 3\%$  of patients treated with LEQVIO and more frequently than placebo) were injection site reaction, arthralgia, and bronchitis.

Please click [here](#) for LEQVIO full Prescribing Information.

## How to use this guide

The first 3 tabs of this guide provide an overview of what you may experience when you refer your patients prescribed LEQVIO<sup>®</sup> to an ASOC for administration. A referral form/checklist tab is included with annotated versions of the form and checklist to help facilitate a referral to an ASOC. Information about the LEQVIO Service Center can be found in the final tab. The referral process is described in 3 simple steps:



Key actions and available resources are called out in each step.

**If you have any questions, contact your Novartis Access and Reimbursement Expert.**

# 1 Locate an ASOC

Once the clinical decision is made to prescribe LEQVIO<sup>®</sup> and you have educated the patient on the drug, you will then have to determine if your office will be administering the drug to the patient. If not, you can refer them to an ASOC.



## KEY ACTIONS

**Communicate to the patient that they will be referred to an ASOC for their LEQVIO dose**



**Find an ASOC that is convenient for your patient by visiting [LEQVIO-locator.com](https://www.leqvio-locator.com)**



**Ensure the patient agrees to the referral and provides any information needed for you to prepare the ASOC referral form**

**[LEQVIO-locator.com](https://www.leqvio-locator.com) can help you find a convenient location for your patient to receive their LEQVIO treatment.**

# The LEQVIO® Locator Tool

Allows you to enter your patient's ZIP Code and find ASOCs in their local area\*

Examples listed here are for illustration only and are not real sites of care.

Access the tool on [LEQVIO-locator.com](https://www.leqvio-locator.com).  
 You can also register your practice as an alternate site of care for LEQVIO at [www.infusioncenter.org/signin/](https://www.infusioncenter.org/signin/).

**Novartis does not recommend the use of any specific ASOC.**

\*The list of sites of care provided in the locator is not comprehensive, and other sites of care may be available to you and your patients. These lists are maintained by a third party, and inclusion in the locator is not an endorsement of any of the sites.

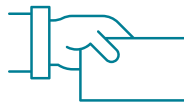
## 2 Refer

Once you have found an ASOC and notified your patient, you will need to send the referral to the ASOC. Each ASOC may have different requirements for a referral, so it is a good idea to check with the ASOC to make sure you have all the correct information prepared before you send the referral.

### Generally, you may need to include:



**Completed referral form, including LEQVIO<sup>®</sup> order**



**Patient insurance information**



**Diagnosis codes, relevant lab values, and treatment history**

**Patients may incur additional out-of-pocket costs if they are referred to an ASOC that is considered "Out-of-Network" by their health plan.**



### KEY ACTIONS

**Complete and submit the referral form with all appropriate clinical documentation and relevant information to the ASOC**



**Contact the ASOC to make sure they received the referral form**



**Reach out to the patient to inform them that they will be receiving a phone call from the ASOC to schedule their appointment. You may also need to contact them if the ASOC needs any more information for the referral**

# Once referred, the ASOC intakes your patient, schedules a visit, and administers LEQVIO<sup>®</sup>

The below represents what you may expect for your patients referred to an ASOC.\* Not every ASOC follows the same process. Make sure to check with the ASOC to confirm their process and follow up with them if you have questions.

## Clinical decision is made to prescribe drug



Decision is made by a health care professional (HCP) to use an ASOC for administration

### ASOC process for patient

**Learn**  
Gain an understanding of their prescribed drug and its administration from the office staff.

**Decide**  
Agree to ASOC referral and provide necessary information to the HCP/office staff so they can send the referral form to the ASOC.

**Schedule**  
ASOC coordinator reaches out to schedule an appointment. Two visits may be required, one as an initial visit and another to receive the injection.

**Arrive**  
Patient arrives at the ASOC to receive the injection.

**Follow plan**  
Patient schedules next injection and continues to follow treatment plan and lifestyle recommendations from their care team.

### ASOC process for practice

**Educate**  
Inform the patient about their prescribed drug and the decision to use an ASOC.

**Locate**  
If the practice is unaligned to a system with an ASOC, search for one through the National Infusion Center Association or contact the drug manufacturer's support program.

**Notify**  
Contact the patient when a location is identified and their order is communicated.

**Refer**  
Send the information to the ASOC. Include the following:

- Completed referral form
- Patient insurance information
- Diagnosis codes

### ASOC

**Receive**  
Acknowledge receipt and ensure all necessary information has been provided by the practice.

**Intake**  
The ASOC calls the patient to welcome and introduce them to their services. The ASOC also reviews the prior authorization (if required), performs a benefits investigation, and connects the patient with financial support.

**Coordinate**  
Schedule visit and perform an initial assessment. This may include patient and caregiver training on what they should expect during and after treatment.

**Administer**

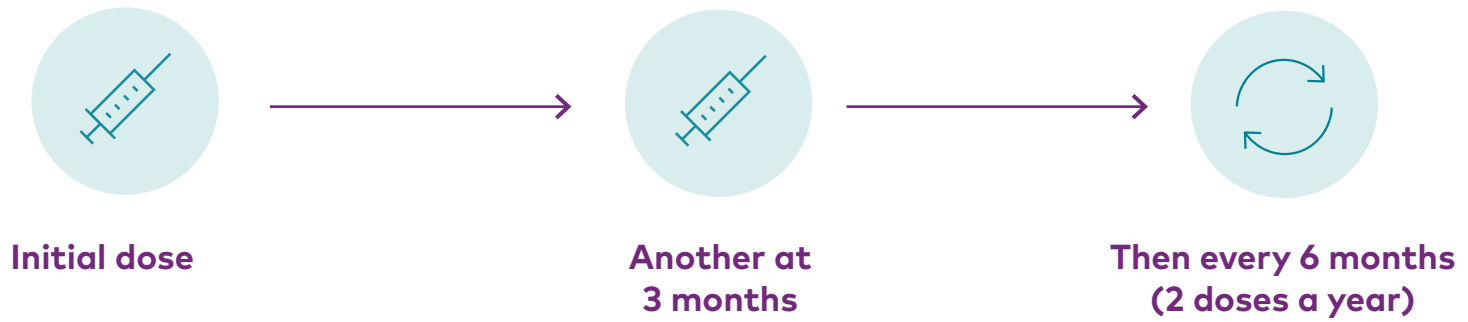
**Follow up**

**Follow up**  
Receive report from the ASOC and continue clinical care of patient. Determine how future checkups and injections are scheduled.

\*Encompasses Infusion Suites, Ambulatory Infusion Centers, and Infusion Management Companies.

### 3 Follow up after administration

Once the patient has received their LEQVIO<sup>®</sup> dose, coordinate with the ASOC regarding future injections.



The ASOC should set up the patient's next appointment once the injection has been administered. Please confirm with the ASOC that subsequent injections have been scheduled.



#### KEY ACTIONS

**Document the date of the patient's LEQVIO administration**



**Consider whether follow-up between appointments may be necessary for your patient**



# Completing the referral/order form

Use this page as a guide when completing a referral/order for your appropriate LEQVIO® patients. **Note:** Ensure the preferred treatment center does not have their own referral/order form before completing this document. It is always the responsibility of the HCP to check with the treatment center to confirm the process for referral and information required.

## Example: for illustrative purposes only

### LEQVIO® Referral/Order Form

If the preferred treatment center does not have its own required referral/order form, you may use this form when referring your LEQVIO patient to help support the order. This form is meant to capture the most common information typically needed by a treatment center. **NOTE: You should check with the treatment center directly to confirm the process for referral and information required before completing this document.**

**INDICATION**  
LEQVIO injection is indicated as an adjunct to diet and statin therapy for the treatment of adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH), to reduce low-density lipoprotein cholesterol (LDL-C).

Preferred treatment center name: Alternate Injection Center Phone: 1-234-567-8910 Fax: 1-012-345-6789

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**PATIENT INFORMATION (please attach patient demographic form if available)**  
 Name: Jane Doe DOB: 09 / 30 / 1950 Address: 321 Main St.  
 City: Anytown State: NY ZIP Code: 10003 Phone: 1-555-555-5555 Email: janedoe@email.com  
 No known drug allergies Allergies: \_\_\_\_\_

**INSURANCE INFORMATION**  
**REQUIRED-Front and back copies of all patient insurance cards: primary, secondary (if applicable), and prescription (if applicable).**  
 Select all that apply:  Primary  Secondary  Prescription/Pharmacy

**PROVIDER INFORMATION**  
 Referring Provider Name: Dr. John Doe NPI #: 1234567890  
 Practice Name: The Doctor's Office Office Contact Name: Joe Smith  
 Address: 123 Anywhere City: Anytown State: NY ZIP Code: 10003  
 Phone: 1-555-123-5555 Fax: 1-555-123-5554 Email: joesmith@email.com

**CLINICAL INFORMATION**  
**1. Primary diagnosis section (must select one; complete ICD-10-CM to highest level of specificity) - REQUIRED**  
 I confirm the patient has been currently receiving statin therapy (or has been determined clinically intolerant) and has been diagnosed with:  
 **E78.2 Hyperlipidemia** (E78.00, E78.2, E78.4, E78.49, E78.5) OR  **E78.01 Familial hypercholesterolemia (eg, HeFH)** OR  **Other (specify ICD-10-CM):** \_\_\_\_\_  
      Z83.42 Family history of familial hypercholesterolemia  
      E75.5 Other lipid storage disorders (approximate synonyms include tendon xanthoma)  
      Other (specify ICD-10-CM): \_\_\_\_\_  
(supporting documents include Simon Broome diagnostic, Dutch Lipid Clinic score, and/or genetic testing)

**2. Secondary diagnosis(es) (please complete if Hyperlipidemia above is selected; complete ICD-10-CM to highest level of specificity) - RECOMMENDED**  
 **Clinical ASCVD:**  I2.\_\_\_\_ Ischemic heart disease  I70.1 Atherosclerosis  Other \_\_\_\_\_  
 I6.\_\_\_\_ Cerebrovascular disease  I73.\_\_\_\_ Other peripheral vascular disease (specify ICD-10-CM): \_\_\_\_\_  E11.\_\_\_\_ Diabetes mellitus  Other \_\_\_\_\_  
 E10.\_\_\_\_ Hypertension (specify ICD-10-CM): \_\_\_\_\_

**3. LDL-C level:**  
 Current level: 190 mg/dL Date taken: 6/21/2023 (MM/DD/YYYY) Current LDL-C lowering treatment(s): Atorvastatin  
 Patient was previously enrolled in an inclisiran clinical trial. Last inclisiran injection date: \_\_\_\_\_

**Patient status and treatment history**  
 Include patient chart notes to support documentation payers may require, such as:  
 • Clinical documentation for specified ICD-10-CM diagnosis codes  
 • Recent comprehensive lipid panel/LDL-C values (in the last 90 days)  
 • Statin history and/or additional lipid-lowering treatment  
 • Statin intolerance (if applicable)  
 • Counseling on the importance of lifestyle modifications including diet and exercise

**LEQVIO ORDER (select all that apply) - Order valid for 1 year from provider signature date**  
 Initial dose →  LEQVIO (inclisiran) 284 mg/1.5 mL subcutaneous initially, then LEQVIO (inclisiran) 284 mg/1.5 mL subcutaneous in 3 months  
 Maintenance dose →  LEQVIO (inclisiran) 284 mg/1.5 mL subcutaneous every 6 months  
 Other →  LEQVIO (inclisiran) 284 mg/1.5 mL subcutaneous \_\_\_\_\_  
 Previous LEQVIO dose given on: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

**PROVIDER SIGNATURE:** Dr. John Doe Date: 08 / 04 / 2023

**IMPORTANT SAFETY INFORMATION**  
 Adverse reactions in clinical trials (≥3% of patients treated with LEQVIO and more frequently than placebo) were injection site reaction, arthralgia, and bronchitis.  
 Please click [here](#) for LEQVIO full Prescribing Information.

Populate the preferred treatment center name and contact information. Make sure you are reaching out to the central intake line, if applicable.

Provide the patient's demographic information or attach a patient demographic form if available.

Include copies of the front and back of the patient's relevant insurance cards and indicate which have been attached.

Include provider details.

Include the appropriate ICD-10-CM diagnosis code(s). A list of codes is available in the LEQVIO [Billing and Coding Guide](#).

Include attachments of relevant patient information, treatment history, and lab values. Including this information helps to prevent delays in treatment.

Complete the LEQVIO order section by selecting all that apply. This information is considered the order and must be checked in order to be processed.

The provider's signature should be included to help ensure there are no delays in treatment.

To download a referral form, click [here](#).

# Completing the clinical documentation referral checklist


When referring a patient to an ASOC, use this checklist along with the referral/order form to help ensure documentation is as complete as possible to avoid treatment delays. **Note:** Ensure the treatment center does not have a separate, required referral/order form before completing the LEQVIO<sup>®</sup> Referral/Order Form.

This checklist is intended to provide examples of what information is usually required. It is always the responsibility of the HCP to check with the treatment center to confirm the process for referral and information required.

**Example: for illustrative purposes only**

## LEQVIO<sup>®</sup> Clinical Documentation Referral Checklist

This checklist is meant to capture the most common information typically needed by a treatment center. Use this checklist to help complete the LEQVIO Referral/Order Form and to ensure necessary clinical information in support of the referral is attached. **NOTE: You should check with the treatment center directly to confirm the process for referral and information required.**



Patient Name: Jane Doe Date of Service: 11/1/2022

**Patient has a primary diagnosis of:**  
 Hyperlipidemia  Heterozygous familial hypercholesterolemia (HeFH)  Other: \_\_\_\_\_

<p><b>If patient has a history of clinical atherosclerotic cardiovascular disease (ASCVD)—select all that apply</b></p> <input type="checkbox"/> Angina, stable or unstable <input type="checkbox"/> Coronary syndrome, acute <input type="checkbox"/> Myocardial infarction, history of <input type="checkbox"/> Revascularization, coronary or other arterial (coronary artery bypass grafting, percutaneous transluminal coronary angioplasty, etc) <input type="checkbox"/> Peripheral arterial disease <input checked="" type="checkbox"/> Positive findings in computed tomography angio or cath <input type="checkbox"/> Stroke <input type="checkbox"/> Transient ischemic attack <input type="checkbox"/> Other: _____	OR	<p><b>If patient has an increased risk of ASCVD—select all that apply</b></p> <input checked="" type="checkbox"/> Age ≥65 years <input type="checkbox"/> History of prior coronary artery bypass surgery or PCI outside of the major ASCVD event(s) <input type="checkbox"/> Diabetes mellitus <input type="checkbox"/> Hypertension <input type="checkbox"/> Chronic kidney disease (eGFR 15-59 mL/min/1.73 m <sup>2</sup> ) <input type="checkbox"/> Current smoking <input type="checkbox"/> Persistently elevated LDL-C (≥100 mg/dL [≥2.6 mmol/L]) despite maximally tolerated statin therapy and ezetimibe <input type="checkbox"/> History of congestive heart failure <input type="checkbox"/> Other: _____	AND/OR	<p><b>If patient has a history of HeFH—select all that apply</b></p> <input type="checkbox"/> Dutch Lipid/WHO Score >8 <input type="checkbox"/> Pretreatment LDL-C ≥190 mg/dL <input type="checkbox"/> First or second degree relative with pretreatment LDL-C ≥190 mg/dL <input type="checkbox"/> Simon Broome diagnostic criteria met <input type="checkbox"/> Other: _____
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Other relevant patient history: \_\_\_\_\_

Relevant ICD-10-CM diagnosis code(s)

**Lab values**  Relevant tests and recent lab values including LDL-C levels >70 mg/dL

**Current and previous lipid-lowering therapy—select all that apply**

Atorvastatin (LIPITOR<sup>®</sup>)  10  20  40  80 ----- Dates/length of use: 2/10/20 - present

Pravastatin (PRAVACHOL<sup>®</sup>)  10  20  40  80 ----- Dates/length of use: \_\_\_\_\_

Simvastatin (ZOCOR<sup>®</sup>)  5  10  20  40  80 ----- Dates/length of use: \_\_\_\_\_

Rosuvastatin (CRESTOR<sup>®</sup>)  5  10  20  40 ----- Dates/length of use: \_\_\_\_\_

Ezetimibe (ZETIA<sup>®</sup>)  10 ----- Dates/length of use: \_\_\_\_\_

Other: \_\_\_\_\_ Dates/length of use: \_\_\_\_\_

Patient had inadequate response to lipid-lowering therapy

**Medical history for statin therapy—select all that apply**

Patient experienced myalgia/myositis that resolved when removed from therapy

Patient has undergone re-challenge with lower dose statin with symptom reappearance

Patient has known contraindications to statins


Patient has creatine phosphokinase elevations >10x upper normal limit

Other: \_\_\_\_\_

<p><b>IMPORTANT SAFETY INFORMATION</b></p> <p>Adverse reactions in clinical trials (≥3% of patients treated with LEQVIO and more frequently than placebo) were injection site reaction, arthralgia, and bronchitis.</p>	<p><b>INDICATION</b></p> <p>LEQVIO injection is indicated as an adjunct to diet and statin therapy for the treatment of adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH), to reduce low-density lipoprotein cholesterol (LDL-C).</p>
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**Please click [here](#) for LEQVIO full Prescribing Information.**

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Populate the patient's name and date of service.

Indicate the patient's primary diagnosis.

Indicate the criteria that have been met to validate the patient's diagnosis.

Provide any other relevant patient history.

Remember to include the appropriate diagnosis code(s) and recent patient lab values.

Provide documentation of the patient's current and previous use of lipid-lowering therapies, if applicable.

Provide the patient's medical history for their statin therapy, if applicable.

To download the clinical documentation referral checklist, click [here](#).

# The LEQVIO<sup>®</sup> Service Center can assist you throughout the access process



## GET STARTED

Register for the Service Center Portal and submit your request online at [ServiceCenterPortal.com](https://ServiceCenterPortal.com)

## OR

Simply download the one-page Start Form and fax it to **877-LEQVIO8 (877-537-8468)**



## GET INSURANCE COVERAGE INFORMATION

Once enrolled, the Service Center will verify benefits to determine patient coverage requirements.

New patients with commercial insurance may be eligible to receive two free LEQVIO doses if coverage is delayed or denied. Limitations apply.\*



## GET FINANCIAL SUPPORT

We'll determine if your patients may be eligible for financial support programs, like the LEQVIO Co-pay Program.

Eligible commercially insured patients may pay as little as \$0.†



## GET PRODUCT

We're here to provide support no matter what product acquisition method you choose:

- Buy-and-bill
- Referral to an ASOC
- Specialty pharmacy



## GET REIMBURSED

After you acquire and administer LEQVIO, we'll provide information and resources to support you through the claim submission process.

\*Terms & Conditions: Eligible patients must have commercial insurance, a valid prescription for LEQVIO, and a prior authorization that has been denied or pending for greater than 3 calendar days. Program provides up to two (2) doses of free medication. Program is not available to patients who are uninsured or whose medications are reimbursed in whole or in part by Medicare, Medicaid, TRICARE, or any other federal or state program, or where prohibited by law. No purchase necessary. Program is not health insurance, nor is participation a guarantee of insurance coverage. Other limitations may apply. Novartis reserves the right to rescind, revoke, or amend the Program and discontinue support at any time without notice.

†Limitations apply. Valid only for those with commercial insurance. The Program may include the Co-pay Card, Payment Card (if applicable), and Rebate. Per treatment maximums and an annual benefit cap apply. For patients covered under the medical benefit, rebate for out-of-pocket costs will be assigned directly to provider, unless patient requests direct reimbursement. Patient is responsible for any costs once limit is reached in a calendar year. Program not valid (i) under Medicare, Medicaid, TRICARE, VA, DoD, or any other federal or state health care program, (ii) where patient is not using insurance coverage at all, (iii) where the patient's insurance plan reimburses for the entire cost of the drug, or (iv) where product is not covered by patient's insurance. The value of this program is exclusively for the benefit of patients and is intended to be credited towards patient out-of-pocket obligations and maximums, including applicable co-payments, coinsurance, and deductibles. Program is not valid where prohibited by law. Patient may not seek reimbursement for the value received from this program from other parties, including any health insurance program or plan, flexible spending account, or health care savings account. Patient is responsible for complying with any applicable limitations and requirements of their health plan related to the use of the Program. Valid only in the United States and Puerto Rico. This Program is not health insurance. Program may not be combined with any third-party rebate, coupon, or offer. Proof of purchase may be required. Novartis reserves the right to rescind, revoke, or amend the Program and discontinue support at any time without notice.

# Stay connected with the LEQVIO<sup>®</sup> Care Program

Through the LEQVIO Care Program, patients will have access to:



**Medication reminders**



**Healthy living tips and tools**



**A dedicated Patient Care Specialist**

Your patient must opt into this program when filling out the LEQVIO Service Center Start Form or calling the Service Center at 833-LEQVIO2 (833-537-8462).

In addition, we offer Next Dose Support for your office and the ASOC, to help ensure any coverage-related requirements are addressed in advance of your patient's next appointment.

## Have questions? We are here to help.



Phone: **833-LEQVIO2 (833-537-8462)**



Fax: **877-LEQVIO8 (877-537-8468)**



Website: **LEQVIO-access.com**



Portal: **ServiceCenterPortal.com**

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