



The LEQVIO® 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[®] (inclisiran) injection is indicated as an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C) in adults with hypercholesterolemia, including heterozygous familial hypercholesterolemia (HeFH).

IMPORTANT SAFETY INFORMATION

LEQVIO is contraindicated in patients with a prior serious hypersensitivity reaction to inclisiran or any of the excipients in LEQVIO. Serious hypersensitivity reactions have included angioedema. 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[®] 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[®] 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://leqvio-locator.com)



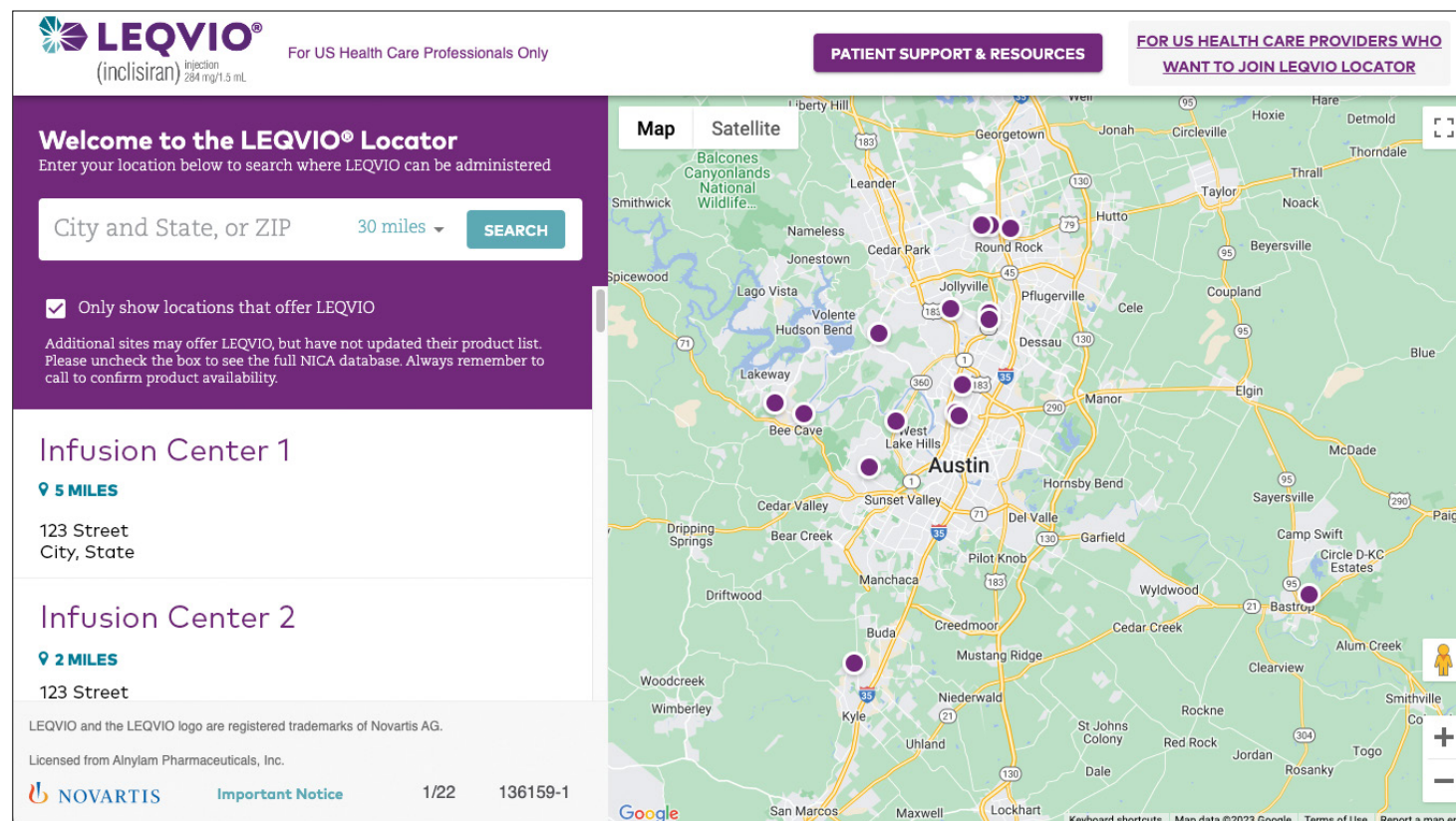
Ensure the patient agrees to the referral and provides any information needed for you to prepare the ASOC referral form

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

1**Locate****2****Refer****3****Follow up****ASOC Referral
Form/Checklist****LEQVIO
Service Center**

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 admin.infusioncenter.org.

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® 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[®]

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

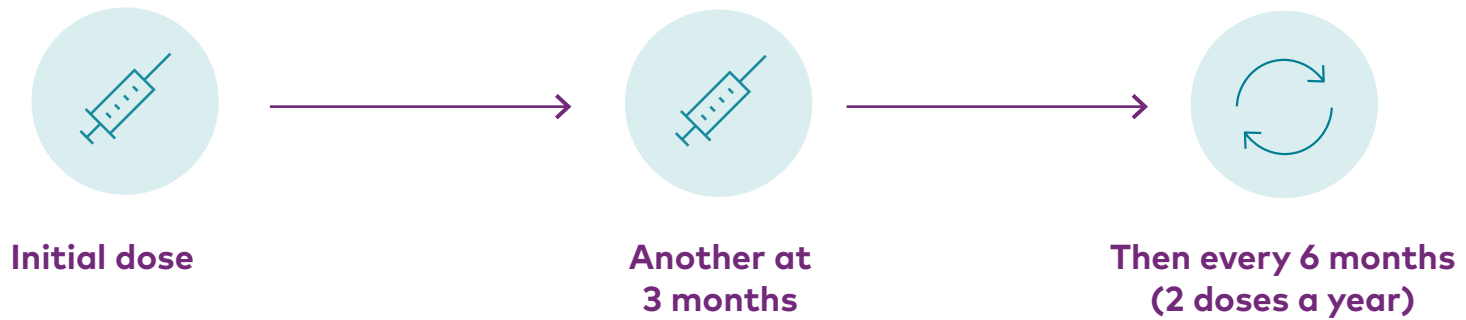
Follow up

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[®] 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 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® 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® 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:
☒ Hypercholesterolemia ☐ Heterozygous familial hypercholesterolemia (HeFH) ☐ Other: _____

<p>If patient has a history of clinical atherosclerotic cardiovascular disease (ASCVD)—select all that apply</p> <p><input type="checkbox"/> Angina, stable or unstable</p> <p><input type="checkbox"/> Coronary syndrome, acute</p> <p><input type="checkbox"/> Myocardial infarction, history of</p> <p><input type="checkbox"/> Revascularization, coronary or other arterial (coronary artery bypass grafting, percutaneous transluminal coronary angioplasty, etc)</p> <p><input type="checkbox"/> Peripheral arterial disease</p> <p><input checked="" type="checkbox"/> Positive findings in computed tomography angio or cath</p> <p><input type="checkbox"/> Stroke</p> <p><input type="checkbox"/> Transient ischemic attack</p> <p><input type="checkbox"/> Other: _____</p>	<p>OR</p>	<p>If patient has an increased risk of ASCVD—select all that apply</p> <p><input checked="" type="checkbox"/> Age ≥65 years</p> <p><input type="checkbox"/> History of prior coronary artery bypass surgery or PCI outside of the major ASCVD event(s)</p> <p><input type="checkbox"/> Diabetes mellitus</p> <p><input type="checkbox"/> Hypertension</p> <p><input type="checkbox"/> Chronic kidney disease (eGFR 15–59 mL/min/1.73 m²)</p> <p><input type="checkbox"/> Current smoking</p> <p><input type="checkbox"/> Persistently elevated LDL-C (≥100 mg/dL [≥2.6 mmol/L])</p> <p><input type="checkbox"/> History of congestive heart failure</p> <p><input type="checkbox"/> Other: _____</p>	<p>AND/OR</p>	<p>If patient has a history of HeFH—select all that apply</p> <p><input type="checkbox"/> Dutch Lipid/WHO Score >8</p> <p><input type="checkbox"/> Pretreatment LDL-C ≥190 mg/dL</p> <p><input type="checkbox"/> First or second degree relative with pretreatment LDL-C ≥190 mg/dL</p> <p><input type="checkbox"/> Simon Broome diagnostic criteria met</p> <p><input type="checkbox"/> Other: _____</p>
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☐ Relevant patient history regarding diet and exercise: _____

☐ Other relevant patient history: _____

☒ Relevant ICD-10-CM diagnosis code(s) _____

Lab values ☒ Relevant tests and recent lab values including LDL-C levels

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

☐ Atorvastatin (LIPITOR®) ☐ 10 ☐ 20 ☒ 40 ☐ 80 ----- Dates/length of use: 2/10/20 - present

☒ Pravastatin (PRAVACHOL®) ☐ 10 ☐ 20 ☐ 40 ☐ 80 ----- Dates/length of use: _____

☐ Simvastatin (ZOCOR®) ☐ 5 ☐ 10 ☐ 20 ☐ 40 ☐ 80 ----- Dates/length of use: _____

☐ Rosuvastatin (CRESTOR®) ☐ 5 ☐ 10 ☐ 20 ☐ 40 ----- Dates/length of use: _____

☐ Ezetimibe (ZETIA®) ☐ 10 ----- Dates/length of use: _____

☐ Other: _____ Dates/length of use: _____

☒ Patient not at recommended target despite 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: _____

IMPORTANT SAFETY INFORMATION

LEQVIO is contraindicated in patients with a prior serious hypersensitivity reaction to inclisiran or any of the excipients in LEQVIO. Serious hypersensitivity reactions have included angioedema. Adverse reactions in clinical trials (≥3% of patients treated with LEQVIO and more frequently than placebo) were injection site reaction, arthralgia, and bronchitis.

Please see accompanying LEQVIO full Prescribing Information.

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INDICATION

LEQVIO injection is indicated as an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C) in adults with hypercholesterolemia, including heterozygous familial hypercholesterolemia (HeFH).

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.

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

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The LEQVIO[®] Service Center is here to assist you along the LEQVIO journey



You can request services in 1 of 2 ways:

Complete the LEQVIO Start Form and fax it to 1-877-LEQVIO8 (1-877-537-8468). You can download the LEQVIO Start Form from LEQVIOhcp.com or request a printed copy from your Novartis Access and Reimbursement Expert.

OR

Register for the Service Center Portal and submit your request online at ServiceCenterPortal.com.



Reminder: to complete their enrollment and receive any of the Novartis Patient Support offerings, patients must provide their consent.



ACCESS AND REIMBURSEMENT

Once enrolled, our team will conduct an insurance coverage review to determine your patient's benefits and financial responsibility.



PATIENT AFFORDABILITY

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.*

Patients can sign up by visiting start.LEQVIO.com or calling **1-833-LEQVIO2 (1-833-537-8462)**, Monday - Friday, 8 AM - 8 PM ET.



SUBMIT AND MANAGE CO-PAY CLAIMS

Manage co-pay claims for reimbursement by:

1. Mailing the completed claim form with the appropriate supporting documentation to LEQVIO Co-pay Program, 77 Corporate Dr, Bridgewater, NJ 08807 or faxing it to 1-908-548-9364. You can download the claim form at LEQVIOhcp.com/resources
2. Filing claims directly through your electronic medical record/billing software
3. Using the LEQVIO Co-pay Portal at LEQVIO-copayportal.com



PATIENT EDUCATION AND ONGOING SUPPORT

Dedicated one-on-one support from the LEQVIO Care Program can help patients start and stay on their LEQVIO treatment. See next page for more details.

***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.

Please see Important Safety Information on page 2 and click [here](#) for LEQVIO full Prescribing Information.

Stay connected with the LEQVIO[®] Care Program

The LEQVIO Care Program can support patients through a dedicated Patient Care Specialist who provides patients with:



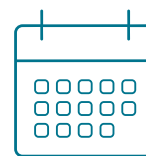
Onboarding support

- Leading up to treatment start and continued support for up to 2 years following first injection



Patient education

- Helpful resources about condition, treatment, and lifestyle management
- Healthy living tips and tools



Medication reminders

- Personalized injection and appointment reminders

Patients will be contacted based on their communication preferences, via call, text, email, or direct mail.

There are 3 ways that patients can enroll in the LEQVIO Care Program:

- 1 Patients can sign up by visiting start.LEQVIO.com.
OR
- 2 Patients can call **1-833-LEQVIO2 (1-833-537-8462)**, Monday - Friday, 8 AM-8 PM ET.
OR
- 3 If you're requesting Access and Reimbursement Support, Novartis Patient Support can enroll eligible patients in the LEQVIO Care Program **if patient consent is provided**.

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

Please see Important Safety Information on page 2 and click [here](#) for LEQVIO full Prescribing Information.

Have questions? We are here to help.



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



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



Website: **LEQVIOhcp.com**



Portal: **ServiceCenterPortal.com**

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