



Your guide to the buy-and-bill process

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

Name: _____ Phone: _____

Title: _____ Email: _____

You can also talk to a dedicated Access Specialist at the LEQVIO[®] Service Center.

Phone: **833-LEQVIO2 (833-537-8462)** Fax: **877-LEQVIO8 (877-537-8468)**

Website: **LEQVIO-access.com** Portal: **ServiceCenterPortal.com**

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



Indication & Important Safety Information

INDICATION

LEQVIO[®] (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.

LEQVIO[®] can be acquired through multiple options

Once LEQVIO is ordered for a clinically appropriate patient, there are 3 options through which LEQVIO can be acquired:



This guide focuses on the buy-and-bill option specifically.

How to use this guide

This guide is meant to help you navigate the buy-and-bill process in 5 simple steps. Each tab is in chronological order and represents a step in the process, from benefits verification through reimbursement. Each section contains helpful information, key considerations, and frequently asked questions (FAQs). Whether you're new to buy-and-bill or just need a quick refresher on the process, keep this guide handy to refer to whenever questions come up.

Have more questions?

Reach out to your Novartis Access and Reimbursement Expert using the information provided on the cover of this guide.

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

1 Verify benefits

Conduct a benefits verification

- Confirm the patient's benefits with their insurance plan
- The LEQVIO[®] Service Center can help verify your patient's benefits. To get started, complete the LEQVIO one-page Start Form*



You may submit the Start Form in 1 of 2 ways:

Through the Service Center Portal at ServiceCenterPortal.com

OR

Via fax at **877-LEQVIO8 (877-537-8468)**

The LEQVIO Start Form can be found on LEQVIO-access.com

- If you submit the Start Form, a statement of benefits (SOB) will be sent to your office within approximately 3 to 5 business days
- Once the SOB is received (via the Portal or fax), it will let you know:
 - If a prior authorization (PA) is required, as well as any plan-specific PA criteria
 - The patient's out-of-pocket costs
 - Methods of acquisition allowed by the health plan
 - Payer site-of-care requirements
 - Billing and coding information

*The Service Center does not guarantee reimbursement. Your office must always confirm information with the plan.

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

Key considerations for a PA (if a PA is required)

- Your patients with traditional Medicare will likely not require a PA to access LEQVIO[®] because Medicare covers medically necessary use of certain outpatient prescription drugs
- Your patients with Medicare Advantage or commercial insurance may need to submit a PA for LEQVIO
- Before submitting a PA, ensure that the patient has met their plan's PA criteria. PA criteria may vary by plan

FAQs

My patient's plan has a PA in place for LEQVIO. What criteria do plans commonly have in place to approve a PA?

PA criteria may vary by plan, but some examples of criteria may include a history of primary hyperlipidemia, including ASCVD, heterozygous familial hypercholesterolemia or an increased risk of ASCVD,* if the patient is taking a statin or additional lipid-lowering treatment, and if the patient's LDL-C level is above guideline-recommended threshold.† Always review and confirm the PA criteria specified by the plan.

My patient's plan does not cover LEQVIO. What should I do next?

If your patient's plan does not cover LEQVIO, you may be able to submit a letter of medical exception to the plan. If it is still not approved after that, you may be able to submit a letter of appeal.

Your Novartis Access and Reimbursement Expert and the LEQVIO Service Center can help provide information and resources regarding the PA submission process

ASCVD, atherosclerotic cardiovascular disease; LDL-C, low-density lipoprotein cholesterol; T2DM, type 2 diabetes mellitus.

*Factors that increase risk of ASCVD include HeFH, T2DM, or 10-year risk of $\geq 20\%$.

†Guideline-recommended LDL-C threshold—ASCVD: < 70 mg/dL; increased risk of ASCVD: < 100 mg/dL.

Access Specialists may help throughout the benefits verification process. They are available Monday through Friday, 8 AM to 8 PM ET, by calling **833-LEQVIO2 (833-537-8462)** or via click-to-chat at [LEQVIO-access.com](https://www.leqvio-access.com).

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

2 Order LEQVIO[®]

LEQVIO Distributors

If you're new to buy-and-bill, it is a good idea to establish an account with accredited distributors before you begin ordering. See the list below for authorized distributors you may use to order LEQVIO.

Distributor	Contact Information	Website
AmerisourceBergen Besse Medical (physician distribution)	Phone: 1-800-543-2111 Fax: 1-800-543-8695	https://www.besse.com
AmerisourceBergen Oncology Supply (practice distribution)	Phone: 1-800-633-7555 Fax: 1-800-248-8205	https://www.oncologysupply.com
AmerisourceBergen Specialty Distribution (health systems and specialty pharmacy)	Phone: 1-800-746-6273 Fax: 1-800-547-9413	https://www.asdhealthcare.com
Anda	Phone: 1-855-297-0081 Fax: 1-855-546-8521	https://www.andanet.com
Cardinal Health Specialty Pharmaceuticals	Phone: 1-866-677-4844	https://specialtyonline.cardinalhealth.com
CuraScriptSD	Phone: 877-599-7748 Fax: 1-800-862-6208	https://curascriptsd.com
Henry Schein	Phone: 1-800-772-4346 Fax: 1-800-329-9109	https://www.henryschein.com
McKesson Medical-Surgical	Phone: 1-866-625-2679	https://mms.mckesson.com
McKesson MPB	Phone: 1-877-625-2566 Fax: 1-888-752-7626	https://connect.mckesson.com
McKesson Specialty Care Distribution	Phone: 1-855-477-9800 Fax: 1-800-800-5673	https://mscs.mckesson.com
Metro Medical (A Cardinal Health Company)	Phone: 1-800-768-2002 Fax: 1-615-256-4194	https://metromedicalorder.com

Novartis does not recommend the use of any particular distributor.

Group Purchasing Organizations (GPOs)

If you intend to work with a GPO, you can order with the following companies:

GPO	Contact Information	Website/Email
Cardinal Health	Phone: 1-800-926-3161	www.cardinalhealth.com
Cornerstone Rheumatology GPO	Phone: 1-800-768-2002	https://www.cardinalhealth.com/cornerstonerheumatology
Specialty Practice Network	Phone: 1-888-536-7697	www.specialtypracticenetwork.com

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

GPOs (cont)

GPO	Contact Information	Website/Email
Matrix GPO	Phone: 1-888-263-9982	https://matrixgpo.com/
MosaicGPO Solutions	Phone: 1-800-768-2002	https://www.cardinalhealth.com/mosaicgpo
Onmark GPO	Phone: 1-800-482-6700	https://www.mckesson.com/Specialty/Group-Purchasing/
Premier	Phone: 1-877-777-1552	https://www.premierinc.com
VitalSource GPO	Phone: 1-877-453-3972	https://www.cardinalhealth.com/vitalsourcegpo
Vizient	Phone: 1-800-842-5146	https://www.vizientinc.com

Novartis does not recommend the use of any particular GPO.

Key considerations for ordering LEQVIO[®]

- Develop methods for separating buy-and-bill inventory, free drug samples, and specialty pharmacy inventory
- Finalize storage logistics for LEQVIO. Remember that LEQVIO can be stored at room temperature. Controlled room temperature is 68-77 °F (20-25 °C) with allowable excursions between 59-86 °F (15-30 °C)
- Prepare to assume financial responsibility for inventory

FAQ

How long does it take to receive LEQVIO after it is ordered?

Most orders arrive in 1 to 3 business days. For a more accurate estimation, confirm with the distributor.

LEQVIO Returns: If you have questions about LEQVIO returns, please contact Novartis Pharmaceuticals Corporation by phone at 1-800-526-0175, or email novartis.phuseh@novartis.com. For returns of product damaged in shipment, please contact your distributor.

Reference: Leqvio. Prescribing information. Novartis Pharmaceuticals Corp.

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

3 Administer LEQVIO[®]

The administration process for LEQVIO includes these important steps:



1. Review the patient's out-of-pocket costs

After you've verified your patient's benefits, you will learn what their out-of-pocket costs will be for LEQVIO. It is important to review this information with the patient before LEQVIO is administered



2. Collect co-pay

Collect the patient's co-pay or coinsurance according to your practice's billing protocols



3. Administer

Patient arrives at your practice and has LEQVIO administered by a health care professional per the Prescribing Information



4. Schedule follow-up

If a patient is in for their initial dose of LEQVIO, schedule them to come back for another dose in 3 months. After that, plan and schedule the patient's next injection for every 6 months



Reference: Leqvio. Prescribing information. Novartis Pharmaceuticals Corp.

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Key considerations for administering LEQVIO[®]

- Establish a routine for collecting co-pay and scheduling follow-up
- Communicate with the LEQVIO Service Center to help ensure patient insurance information is up to date. If their insurance has changed, you will have to reverify their benefits

FAQs

Can patients self-administer LEQVIO?

No. LEQVIO must be administered by a health care professional.

Where can I find co-pay support for my patient?

- Your eligible patients with commercial insurance may pay as little as \$0 for LEQVIO. No financial information required. Subject to terms and conditions. Limitations apply.*
 - Enroll your patient in the co-pay program and manage claims for reimbursement in one of two ways:
 - **Service Center Portal (or via fax):** Access to co-pay and all other services in one place, including benefits verification, prior authorization/appeals support, product acquisition, and billing/coding support
- OR**
- **Co-pay Portal:** Access to co-pay savings, submission for co-pay claims, and tracking payment status



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



Service Center Portal: ServiceCenterPortal.com
Co-pay Portal: LEQVIO-CopayPortal.com

***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.

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4 Submit claim

To submit a claim to get reimbursed for LEQVIO[®] and related services, you may have to fill out either a CMS-1500 or a CMS-1450 (UB-04) claim form. A CMS-1500 form is used when billing prescribed medications administered in HCP offices. The CMS-1450 is used when billing prescribed medications administered in hospital outpatient settings.

Information that may be used for LEQVIO claim submission*

Healthcare Common Procedure Coding System (HCPCS) level II^{1,2}	J1306: Injection, inclisiran, 1 mg JZ modifier: Effective July 1, 2023, providers and suppliers are required to report the JZ modifier on all claims that bill for drugs from single-dose containers that are separately payable under Medicare Part B when there are no discarded amounts
Billing Units	284
Current Procedural Terminology (CPT) code³	96372: Therapeutic, Prophylactic, and Diagnostic Injection (specific substance or drug; subcutaneous or intramuscular)
ICD-10-CM⁴	<p>Below are potential diagnoses and codes that may apply to LEQVIO.</p> <p>Primary diagnosis Hyperlipidemia</p> <ul style="list-style-type: none"> Hyperlipidemia (E78.00, E78.2, E78.4, E78.49, E78.5) <p>HeFH</p> <ul style="list-style-type: none"> Familial hypercholesterolemia (E78.01) Other lipid storage disorders (E75.5) <p>Secondary diagnosis Clinical ASCVD</p> <ul style="list-style-type: none"> Ischemic heart disease (I20-I25.XX) Cerebrovascular disease (I63.XX, I65-I67.XX) Atherosclerosis (I70.XX) Other peripheral vascular disease (I73.89 or I73.9) <p>Increased risk of ASCVD[†]</p> <ul style="list-style-type: none"> Type 2 diabetes mellitus (E11) Chronic kidney disease (N18) Essential (primary) hypertension (I10) <p>• Family history of familial hypercholesterolemia (Z83.42)</p> <p>For a list of potential codes, please see the Billing & Coding Guide.</p>
Patient population⁵	Patient must be diagnosed with primary hyperlipidemia including HeFH, currently receiving statin therapy (or has been determined clinically intolerant), and has not reached LDL-C target (ASCVD: LDL-C <70 mg/dL; increased risk of ASCVD: LDL-C <100 mg/dL)
National Drug Code (NDC) number	10-digit format: 0078-1000-60 11-digit format: 00078-1000-60

Please note: The 3-digit ICD-10-CM codes are not complete codes on their own. To appropriately code these diagnoses in the required format, please reference the International Classification of Diseases, Tenth Revision code manual.

Reference the Billing & Coding Guide on the LEQVIO Service Center website at [LEQVIO-access.com](https://www.leqvio-access.com) to determine appropriate codes to use on claim forms.

ASCVD, atherosclerotic cardiovascular disease; HeFH, heterozygous familial hypercholesterolemia; LDL-C, low-density lipoprotein cholesterol; T2DM, type 2 diabetes mellitus.

*Novartis does not guarantee payment or coverage for any product or service. It is always the provider's responsibility to determine the appropriate health care setting, and to submit true and correct claims for the products and services rendered.

†Factors that increase risk of CVD include HeFH, T2DM, or 10-year risk of $\geq 20\%$. This is not an exhaustive list of factors, and there may be additional factors that contribute to an increased risk of ASCVD.

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References: **1.** Centers for Medicare & Medicaid Services. CMS HCPCS Application Summaries and Coding Recommendations: First Quarter, 2022 HCPCS Coding Cycle. Accessed April 13, 2023. <https://www.cms.gov/files/document/2022-hcpcs-application-summary-quarter-1-2022-drugs-and-biologicals.pdf> **2.** Centers for Medicare & Medicaid Services. Medicare program: discarded drugs and biologicals—JW modifier and JZ modifier policy frequently asked questions. Accessed May 17, 2023. <https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf> **3.** AAPC Coder. Accessed April 13, 2023. <https://coder.aapc.com/cpt-codes/96372> **4.** Centers for Medicare and Medicaid Services. 2022 ICD-10-CM. Accessed April 13, 2023. <https://www.cms.gov/medicare/icd-10/2022-icd-10-cm> **5.** Leqvio. Prescribing information. Novartis Pharmaceuticals Corp.

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Key considerations for filing a claim

- Understand current commercial and Medicare Advantage contracts for permanent J-code rate of reimbursement
- Include the appropriate number of billing units for LEQVIO[®]: 284 mg=284 billing units in Box 24G of the CMS-1500 form and Box 46 of the CMS-1450 form
- Ensure the JZ modifier is used with the J-code for all claims after July 1, 2023
- Contact the insurance plan directly to check the status of the claim

FAQs

Can my Novartis Access and Reimbursement Expert help me fill out a claim form if I need help?

No, a Novartis Access and Reimbursement Expert or other Novartis representatives may not fill out a claim form on your behalf, but they may answer questions you have throughout the process.

Are these the only codes I have to be aware of for LEQVIO?

Information specific to billing and coding is subject to change without notice and should be verified by the provider for each patient prior to treatment. A provider should contact the patient's payer directly for any revised or additional requirements, information, or guidance.

How soon after service do I need to submit a claim?

The suggested timeline for submitting a claim is 24 to 48 hours between service being provided and billing for it.

Is there a way to check on the status of a claim?

To check the status of a claim, contact the insurance plan directly.

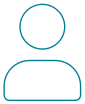
Have more questions?

Reach out to your Novartis Access and Reimbursement Expert or an Access Specialist at the LEQVIO Service Center if you have any questions about submitting a claim.

5 Manage reimbursement



Understand your reimbursement rate based on the plan contract in place.



Allocate an experienced staff member to submit and track reimbursement claims.



Review the remittance advice—also referred to as an explanation of benefits (EOB)—to ensure appropriate payment once received.



If your claim is denied, there is an appeals process that you can follow to help get the claim approved. Contact the LEQVIO[®] Service Center and **see the PA and Appeals Guide on [LEQVIO-access.com](https://www.leqvio-access.com)** for more information.

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Key considerations for managing reimbursement

- Understand your reimbursement rate based on the plan contract and published fee schedules. Review these rates and fee schedules on a quarterly basis in case there is an update
- Dedicate staff members to track billing and scheduling
- Establish a reconciliation process to ensure all of the consumed inventory is captured in the billing process
- Audit claims on a regular basis
- Make certain that accounts receivable match the accounts payable

FAQ

What happens if my claim is denied?

If the insurance plan does not cover LEQVIO[®], a clinician can file a first-level appeal.

Have more questions?

Contact your Novartis Access and Reimbursement Expert or an Access Specialist at the LEQVIO Service Center if you have any questions throughout the reimbursement process.

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The LEQVIO[®] 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

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 alternate site of care
- Specialty pharmacy



GET REIMBURSED

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

*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.

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Stay connected with the LEQVIO[®] 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 may opt into this program when filling out the LEQVIO Service Center [Start Form](#) or by calling the Service Center at **833-LEQVIO2 (833-537-8462)**.

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.

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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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