



Prior authorization and appeals guide

Supporting you through the PA and appeals process for LEQVIO[®]

For questions or support, contact your Novartis Access and Reimbursement Expert

Name: _____ Phone: _____

Title: _____ Email: _____

The information herein is provided for educational purposes only. Novartis cannot guarantee insurance coverage or reimbursement. Coverage and reimbursement may vary significantly by payer, plan, patient, and setting of care. It is the sole responsibility of the health care provider to ensure the accuracy of all statements used in seeking coverage and reimbursement for an individual patient.

PA, prior authorization.

Have questions? Talk to a dedicated Access Specialist.



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



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



Website: **LEQVIOhcp.com**



Portal: **ServiceCenterPortal.com**

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How to use this guide


Since every plan manages LEQVIO® differently, you may run into various restrictions to coverage even if prescribing LEQVIO is the right decision clinically.

This guide is intended to be a resource for you to use if your patient is faced with common insurance restrictions like a prior authorization (PA), step edit, or a plan not having a policy in place for LEQVIO. Tools like the Sample Letter of Medical Necessity and its checklist may help with ensuring your communications with health plans are as complete as possible and support you in getting access to LEQVIO for your patients who need it.

Benefits verification


After determining that LEQVIO is the right treatment for your patient, confirm if the patient's health plan provides coverage for LEQVIO. Your practice should contact the health plan to understand your patient's specific coverage criteria. You may also enroll your patient in the LEQVIO Service Center, where dedicated Access Specialists can verify your patient's benefits and provide other helpful information and resources throughout the LEQVIO access process.

You have two options for enrolling a patient in the program



You can electronically enroll patients in support services at [ServiceCenterPortal.com](https://www.servicecenterportal.com).

OR



Complete the one-page [Start Form](#) and fax it to the LEQVIO Service Center at **877-537-8468**.

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

Typical drug coverage policies

PA Required

A PA is needed to confirm certain criteria have been met. A plan may also have step-edit restrictions in place that need to be met.

OR

Submit a plan-specific PA form requesting LEQVIO.

OR

Not Covered

Coverage may not be granted because:

- LEQVIO is excluded from the health plan's formulary or a coverage decision was not made

OR

If LEQVIO is not covered by the plan, submit a letter of medical necessity or medical exception. If that is not accepted, submit a letter of appeal.

OR

Approved

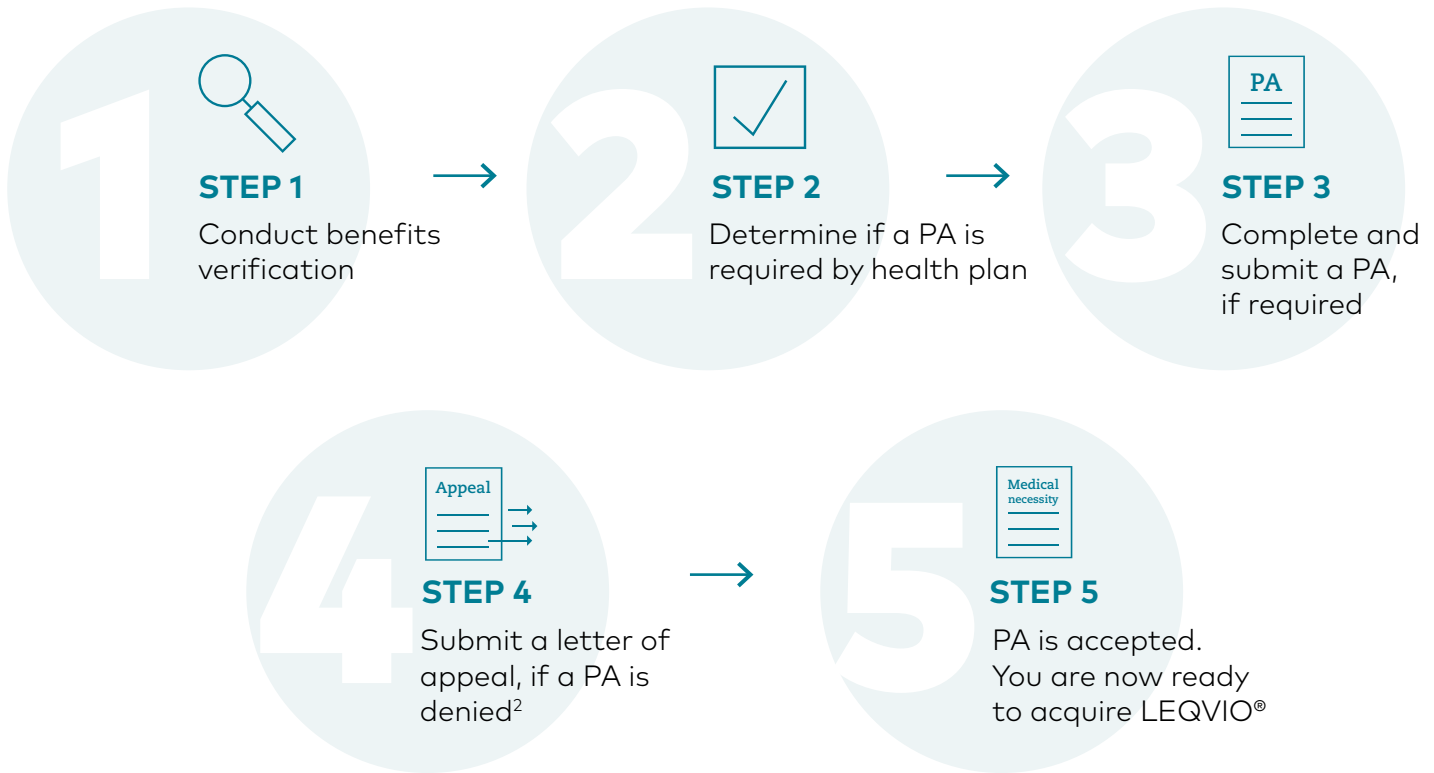
LEQVIO is covered with no restrictions by the plan for the patient.

OR

No further action is needed on your part.

Benefits verification and the PA process

A benefits verification is a process in which a patient’s benefits from their health insurance provider are confirmed to determine coverage. A PA/precertification is a step that a health plan may require to validate coverage and reimbursement for a therapy. Together, benefits verifications and PAs play vital roles in the early stages of the reimbursement process.¹



It is important to address the specific reason for denial of coverage

NOTE: There are multiple levels of appeal. The sample letters included in this guide can be adapted for higher-level appeals.³ Each health plan has their own requirements for each level, so you should check with the plan to determine exactly how you should proceed with your appeal.

You can access the sample letters described above within this guide or by visiting [LEQVIOhcp.com/resources](https://www.leqviohcp.com/resources).

References: **1.** Outsource Strategies. Importance of Insurance Verification. Accessed August 7, 2025. <https://www.outsourcestrategies.com/resources/importance-insurance-verification/> **2.** Forward Health. Denied Requests. Accessed August 7, 2025. <https://www.forwardhealth.wi.gov/WIPortal/Subsystem/KW/Print.aspx?ia=1&p=1&sa=84&s=3&c=15&nt=Denied+Requests> **3.** CGS Medicare. The Appeals Process. Accessed August 7, 2025. <https://www.cgsmedicare.com/jc/redeterminations/appeals-process.html>

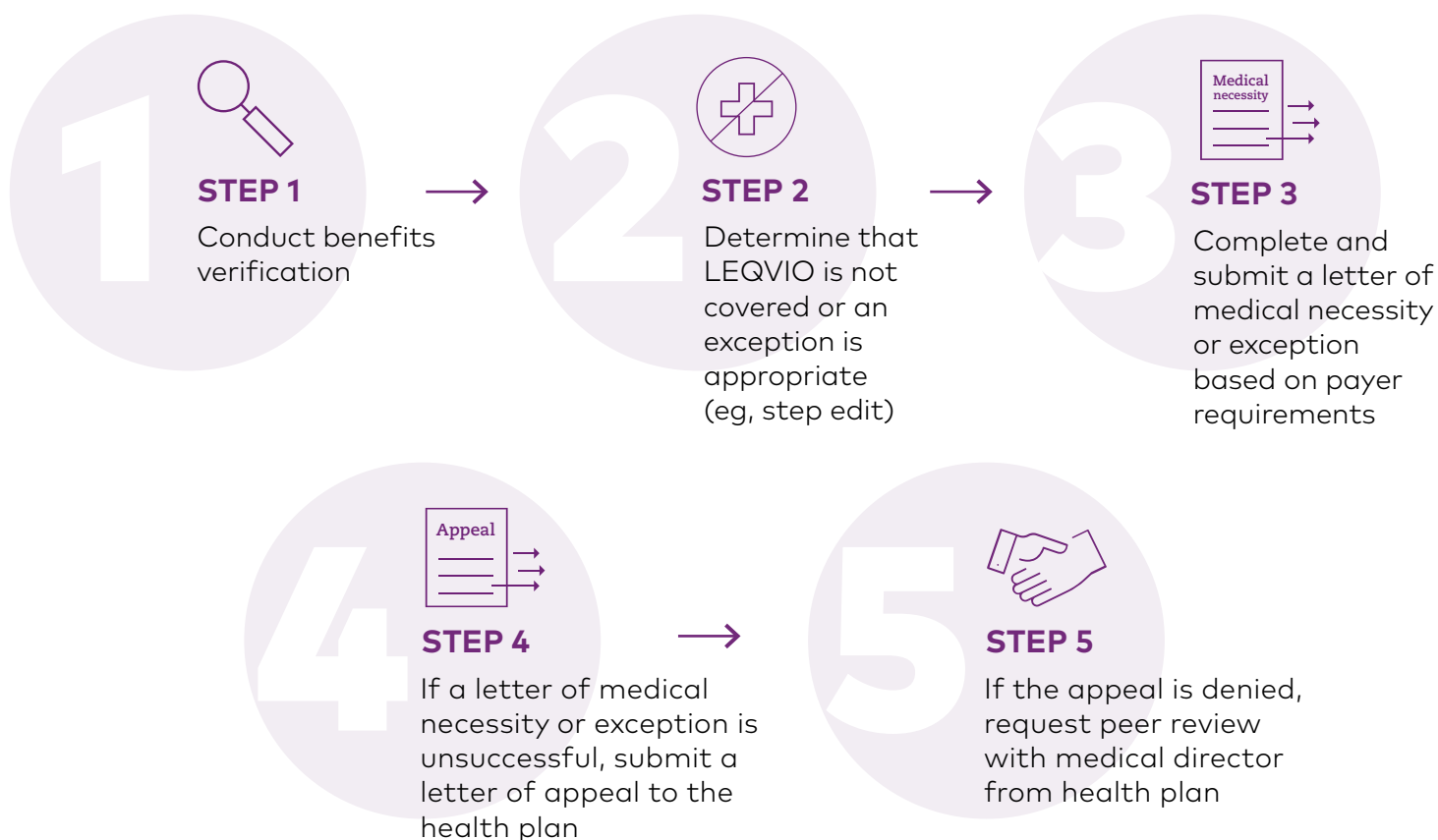
The medical necessity/exception process

Medical necessity:

If your patient's health insurance provider does not grant them access to LEQVIO® due to plan requirements, a letter of medical necessity along with documentation of clinical need may be required to gain access.

Medical exception:

If your patient's health insurance provider excludes or has not made a coverage decision on LEQVIO, a medical exception process may be followed to determine payer coverage. At a minimum, this will require you to submit a letter of medical exception along with documentation of clinical need.



You can access the sample letters described above within this guide or by visiting LEQVIOhcp.com/resources.

Benefits verification and PA checklist

Consider the following points when discussing the benefits verification with the health plan and preparing to submit a PA.

- **Verify patient eligibility and benefits with the health plan before providing LEQVIO®**
- **Before submitting a PA, ensure that the patient has fulfilled the plan's requirements. PA criteria vary by plan, but the list below includes examples of the kinds of PA criteria that plans may have in place:**

For adult patients (aged 18+ years)

- The patient has a primary diagnosis of hypercholesterolemia or heterozygous familial hypercholesterolemia (HeFH)
- The patient has a history of clinical atherosclerotic cardiovascular disease (ASCVD)
 - Acute coronary syndromes
 - History of myocardial infarction (MI)
 - Stable or unstable angina
 - Coronary or other arterial revascularization
 - Stroke or transient ischemic attack (TIA)
 - Peripheral arterial disease (PAD)
- The patient has an increased risk of ASCVD
 - Age ≥ 65 years
 - Type 2 diabetes mellitus
 - 10-year ASCVD risk score of $\geq 20\%$
- The patient is taking a statin or additional lipid-lowering treatment, or has a documented statin intolerance
- The patient's LDL-C level is >70 mg/dL for ASCVD or >100 mg/dL for increased risk of ASCVD
- To be prescribed by, or in consultation with, a primary care physician, cardiologist, endocrinologist, lipidologist, or specialist

For pediatric patients (aged 12-17 years)

- The patient has a primary diagnosis of HeFH or homozygous familial hypercholesterolemia (HoFH)

IMPORTANT SAFETY INFORMATION

Contraindication: LEQVIO (inclisiran) is contraindicated in patients with a prior serious hypersensitivity reaction to inclisiran or any of the excipients in LEQVIO. Serious hypersensitivity reactions have included anaphylaxis and angioedema.

Hypersensitivity Reactions: Hypersensitivity reactions, including anaphylaxis and angioedema, have been reported in patients treated with LEQVIO. Advise patients on the signs and symptoms of hypersensitivity reactions and instruct patients to seek medical attention promptly.

Adverse Reactions: Adverse reactions in clinical trials ($\geq 3\%$ of adult patients treated with LEQVIO and more frequently than placebo) were injection site reaction, arthralgia, and bronchitis. The safety profile in pediatric patients aged 12 years and older with HeFH or HoFH was consistent with adult patients with hypercholesterolemia, except for a higher frequency of headache in pediatric patients with HeFH.

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

Common causes for coverage denials

Be sure to double check your documentation to avoid these common causes for denial.

<p>Administrative information and documentation</p>	<ul style="list-style-type: none"> • Missing patient information (name, date of birth, insurance ID number, insurance group number, and dates of service) • Missing physician's signature • Insufficient/incomplete or incorrect information
<p>Diagnosis</p>	<ul style="list-style-type: none"> • Clerical error resulting in incorrect ICD-10 code • Lack of relevant ICD-10 code(s) • Lack of documentation supporting appropriate diagnosis • Incorrect dosage or unit listed
<p>Lab values</p>	<ul style="list-style-type: none"> • Outdated lab panels (per payer requirement or in the last 90 days) • Submission of lipid profiles without LDL-C levels
<p>History of lipid-lowering therapies</p>	<ul style="list-style-type: none"> • Insufficient duration of prior therapy • No reason provided for discontinuation of previous therapy/therapies

Avoid further delays in treatment

Ensure all requested PA information is accurately completed, if applicable, including prior treatment history, testing history, and ICD-10 code(s). In the event a health plan denies the request for coverage, your office may submit an appeal on behalf of the patient.

For additional information and support, contact your Novartis Access and Reimbursement Expert or visit [LEQVIOhcp.com](https://www.leqvio.com).

Reference: Signature Performance. Understanding the difference between denied and rejected medical claims. Accessed August 7, 2025. <https://www.signatureperformance.com/post/understanding-the-difference-between-denied-and-rejected-medical-claims>

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



LEQVIO®: the first and only siRNA for lowering LDL-C



Refer to this page along with the prescribing information when writing a letter of appeal or medical necessity

FDA approval date	December 21, 2021
Indication	LEQVIO injection is indicated as an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C) in adults with hypercholesterolemia, adults and pediatric patients aged 12 years and older with heterozygous familial hypercholesterolemia (HeFH), and pediatric patients aged 12 years and older with homozygous familial hypercholesterolemia (HoFH).
PCSK9 inhibitor	LEQVIO is the only entrant in the PCSK9 inhibitor class that is a siRNA therapy approved to lower LDL-C.
Dosing & administration	The recommended dosage of LEQVIO is 284 mg/1.5 mL administered by a health care professional as a single subcutaneous injection initially, again at 3 months, then every 6 months. Do not remove the needle cap until you are ready to inject.*
Clinical trials	Three studies were conducted in adult patients with ASCVD (ORION-10 and ORION-11), those at increased risk of ASCVD (ORION-11), and those with HeFH (ORION-9). Two studies were conducted in pediatric patients: ORION-16 for those with HeFH and elevated LDL-C, and ORION-13 for those with HoFH and elevated LDL-C.
Efficacy	<ul style="list-style-type: none"> • In the ORION-10 clinical trial on top of a maximally tolerated statin, LEQVIO demonstrated 52% LDL-C reduction vs placebo at Month 17 (95% CI: -56%, -49%; $P < .0001$) in adult ASCVD patients • In the ORION-11 clinical trial on top of maximally tolerated statin, LEQVIO demonstrated 50% LDL-C reduction vs placebo at Month 17 (95% CI: -53%, -47%; $P < .0001$) in adult ASCVD patients and patients at increased risk of ASCVD • In the ORION-9 clinical trial on top of a maximally tolerated statin, LEQVIO demonstrated 48% LDL-C reduction vs placebo at Month 17 (95% CI: -54%, -42%; $P < .0001$) in adult patients with HeFH • In the ORION-16 clinical trial on top of a maximally tolerated statin, LEQVIO demonstrated 29% reduction vs placebo at month 17 (95% CI: -36%, -21%; $P < .0001$) in pediatric patients aged 12 years and older with HeFH • In the ORION-13 clinical trial on top of LDL-C-lowering therapies, LEQVIO demonstrated 33% reduction vs placebo at month 17 (95% CI: -80%, -13%; $P < .0001$) in pediatric patients aged 12 years and older with HoFH
Safety	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 anaphylaxis and 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. The safety profile in pediatric patients aged 12 years and older with HeFH or HoFH was consistent with adult patients with hypercholesterolemia, except for a higher frequency of headache in pediatric patients with HeFH.

ASCVD, atherosclerotic cardiovascular disease; CI, confidence interval; PCSK9, proprotein convertase subtilisin/kexin type 9; siRNA, small interfering ribonucleic acid.

*For detailed instruction on administration, see Instructions for Use.

Reference: Leqvio. Prescribing information. Novartis Pharmaceuticals Corp.

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



Letter of medical necessity checklist

If your patient's health insurance provider has coverage restrictions in place for LEQVIO®, a letter of medical necessity may be used to ensure your patients who need LEQVIO are able to receive it.

The checklist below is provided to help ensure your letter of medical necessity is as complete as possible when communicating with health plans. The following page contains a sample letter that you may reference when crafting your own letter to the patient's health plan. The checklist and sample letter are intended to provide examples of what information is usually required.

- Include patient's name, date of birth, insurance ID number, insurance group number, and dates of service**
- Include relevant ICD-10 code(s) to support your diagnosis. Visit [LEQVIOhcp.com/practice-resources](https://www.leqviohcp.com/practice-resources) for more information on coding, or see the [Billing and Coding Guide](#) at [LEQVIOhcp.com/resources](https://www.leqviohcp.com/resources) for examples of codes that may be relevant to LEQVIO**
- Clearly state the rationale for treatment with LEQVIO and why it is appropriate for the patient**
- List current and previous therapies, or if the patient is intolerant to current therapies. Confirm that the patient has not achieved adequate results from current or prior therapy**
- Provide clinical support for your recommendation. This can include information such as:**
 - Clinical trial data from the [LEQVIO Prescribing Information](#)
 - Test results and chart notes (eg, LDL-C levels)
 - Relevant patient history regarding diet and exercise
 - Additional medical records
- Summarize your recommendation and provide a phone number in case any additional information is needed**

For additional information and support, contact your Novartis Access and Reimbursement Expert or visit [LEQVIOhcp.com](https://www.leqviohcp.com).

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

Sample letter of medical necessity

Sample Letter of Medical Necessity

Note to physician: this template may be used to help create your institution's independent letter of medical necessity to be sent to a patient's health plan to obtain a prior authorization decision from a health plan and/or in the event that there is a denial of coverage for LEQVIO. All blue content describes the kind of information typically required and is not intended to be included in your final letter of appeal. All pink/bracketed content needs to be filled out based on the details of each specific appeal. Be sure to review and understand specific health plan requirements for your patient. It is also important to understand each plan's submission process (online vs fax).

[Date]

[Health plan name] (Patient's Name)

ATTN: [Department] (Patient's plan-specific member ID)

[Medical/Pharmacy Director Name (if available)] (Date of birth)

[Health plan address] (Case number)

[City, State, ZIP Code] (Dates of service)

Re: Letter of Medical Necessity for LEQVIO® (inclisiran)

Dear [Medical/Pharmacy Director Name],

I am writing this letter of medical necessity on behalf of [Patient's Name] to request coverage for LEQVIO® for the treatment of **[[ADULT PATIENTS AGED 18+] hypercholesterolemia or familial hypercholesterolemia (HeFH) / [PEDIATRIC PATIENTS AGED 12-17] familial hypercholesterolemia (HeFH/HoFH)]**, to reduce low-density lipoprotein cholesterol (LDL-C) **[insert ICD-10 code(s)]**. This letter provides the clinical rationale and relevant information about the patient's medical history and treatment.

I have been treating [Patient's Name], [a/an] [age]-year-old [male/female], since [Date] to manage their high LDL-C levels. My rationale for prescribing LEQVIO is: **[Include relevant medical information and why LEQVIO is the most appropriate treatment option. An example may include evidence that statin therapy alone has not been effective enough, or the patient has high LDL-C levels. If applicable, provide specific information regarding the treatments this patient has already received. Additionally, detail relevant patient history regarding diet and exercise.]**

In my medical judgment, this patient is an appropriate candidate for treatment with LEQVIO. I have included the full Prescribing Information for LEQVIO, as well as supporting clinical data.

If you have any further questions about this matter, please feel free to contact me at **[physician phone number]** or via email at **[physician email]**. Thank you for your time and consideration.

Sincerely,

[Physician's signature] [Physician name] [Physician NPI] [Name of practice] [Phone number]

Enclosures: **[List and attach additional documents, which may include Prescribing Information, clinical notes/medical records, clinical studies and efficacy data, PA number, and/or clinical practice guidelines.]**

This letter is provided as an example and is meant for educational purposes only. Novartis cannot guarantee insurance coverage or reimbursement. Coverage and reimbursement may vary significantly by payer, plan, patient, and setting of care. It is the sole responsibility of the health care provider to include the proper information and ensure the accuracy of all statements used in seeking coverage and reimbursement for an individual patient.

• Include patient's name, date of birth, insurance ID number, insurance group number, and dates of service.

• Include relevant ICD-10 code(s).

List current and previous therapies, or if the patient is intolerant to current therapies. Confirm that the patient has not achieved treatment goals from current or existing therapy.

• It may be helpful to include the LEQVIO® Prescribing Information and data from the LEQVIO clinical trial(s) to support your decision.

• Include PA number, FDA indication, and product information.

You can also download this resource by visiting LEQVIOhcp.com/resources.

If you have any questions about the letter of medical necessity, contact your Novartis Access and Reimbursement Expert.

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



Letter of medical exception checklist

If your patient's health insurance provider excludes or has not made a coverage decision on LEQVIO[®], a letter of medical exception may be used to ensure your patients who need LEQVIO are able to receive it.

The checklist below is provided to help ensure your letter of medical exception is as complete as possible when communicating with health plans. The following page contains a sample letter that you may reference when crafting your own letter to the patient's health plan. The checklist and sample letter are intended to provide examples of what information is usually required.

- Include patient's name, date of birth, insurance ID number, insurance group number, and dates of service**
- Include relevant ICD-10 code(s) to support your diagnosis. Visit [LEQVIOhcp.com/practice-resources](https://www.leqviohcp.com/practice-resources) for more information on coding, or see the [LEQVIO Billing and Coding Guide at LEQVIOhcp.com/resources](https://www.leqviohcp.com/resources) for examples of codes that may be relevant to LEQVIO**
- Clearly state the rationale for treatment with LEQVIO and why it is appropriate for the patient**
- List current and previous therapies, or if the patient is intolerant to current therapies. Confirm that the patient has not achieved adequate results from current or prior therapy**
- Detail relevant patient history regarding diet and exercise**
- Provide clinical support for your recommendation. This can include information such as:**
 - Clinical trial data from the [LEQVIO Prescribing Information](#)
 - Test results and chart notes (eg, LDL-C levels)
 - Additional medical records
- Summarize your recommendation and provide a phone number in case any additional information is needed**

For additional information and support, contact your Novartis Access and Reimbursement Expert or visit [LEQVIOhcp.com](https://www.leqviohcp.com).

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

Sample letter of medical exception

Sample Letter of Medical Exception

Note to physician: this template may be used to help create your institution's independent letter of medical exception to be sent to a patient's health plan should a letter of medical exception be required by a patient's health plan to determine/request coverage. All blue content describes the kind of information typically required and is not intended to be included in your final letter of appeal. All pink/bracketed content needs to be filled out based on the details of each specific appeal. Be sure to review and understand specific health plan requirements for your patient. It is also important to understand each plan's submission process (online vs fax).

[Date] [Patient's Name]
 [Health plan name] [Patient's plan-specific member ID]
 ATTN: [Department] [Patient's date of birth]
 [Medical/Pharmacy Director Name (if available)] [Case number]
 [Health plan address] [Dates of service]
 [City, State, ZIP Code]

Re: Letter of Medical Exception for LEQVIO® (inclisiran)
 Dear [Medical/Pharmacy Director Name],

I am writing this letter of medical exception on behalf of [Patient's Name] to request coverage for LEQVIO® for the treatment of [[ADULT PATIENTS AGED 18+] hypercholesterolemia or familial hypercholesterolemia (HeFH) / [PEDIATRIC PATIENTS AGED 12-17] familial hypercholesterolemia (HeFH/HoFH)], to reduce low-density lipoprotein cholesterol (LDL-C) [insert ICD-10 code(s)]. This letter provides the clinical rationale and relevant information about the patient's medical history and treatment.

I have been treating [Patient's Name], [a/an] [age]-year-old [male/female], since [Date] to manage their high LDL-C levels. My rationale for prescribing LEQVIO is: [Include relevant medical information and why LEQVIO is the most appropriate treatment option. An example may include evidence that previous therapies have not been effective enough, or the patient has high LDL-C levels. If applicable, provide specific information regarding the treatments this patient has already received. Additionally, detail relevant patient history regarding diet and exercise.]

In my medical judgment, this patient is an appropriate candidate for treatment with LEQVIO. I have included the full Prescribing Information for LEQVIO, as well as supporting clinical data.

If you have any further questions about this matter, please feel free to contact me at [physician phone number] or via email at [physician email]. Thank you for your time and consideration.

Sincerely,
 [Physician's signature] [Physician name] [Physician NPI] [Name of practice] [Phone number]

Enclosures: [List and attach additional documents, which may include Prescribing Information, clinical notes/medical records, clinical studies and efficacy data, and/or clinical practice guidelines.]

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

• Include patient's name, date of birth, insurance ID number, insurance group number, and dates of service.

• Include relevant ICD-10 code(s).

• List current and previous therapies, or if the patient is intolerant to current therapies. Confirm that the patient has not achieved treatment goals from current or existing therapy.

• It may be helpful to include the LEQVIO® Prescribing Information and data from the LEQVIO clinical trial(s) to support your decision.

• Include FDA indication and product information.

You can also download this resource by visiting LEQVIOhcp.com/resources.

If you have any questions about the letter of medical exception, contact your Novartis Access and Reimbursement Expert.

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



Letter of appeal checklist

If a plan covers LEQVIO® with a PA and your patient is denied coverage after you submit one, you may explain your clinical rationale for prescribing LEQVIO through a letter of appeal. This letter should address each specific reason for the denial and demonstrate why the health plan’s existing formulary or coverage policy does not represent the most appropriate treatment for the patient.¹

Below is a checklist you can reference to help make sure you capture every important aspect of the appeal in your letter. The following page contains a sample letter of appeal with annotations showing the type of information that will usually be required.

Keep in mind there can be multiple levels of appeal, and you should refer to the health plan’s specific appeal guidelines. There are 5 levels of appeal of PA denials. Each level has its own specific timelines and requirements.²

- Denial information, including the denial letter(s) or explanation of benefits notification
- Patient’s name, date of birth, insurance ID number, insurance group number, and dates of service
- PA/case number
- Patient’s medical records and accompanying ICD-10 code(s)
- Copies of additional medical information
- Clinical support for prescribing LEQVIO
- A list of current and previous therapies and their duration
 - Explain why other treatments are not helping the patient achieve treatment goals
- A letter of medical necessity and the [Prescribing Information](#) for LEQVIO
- Additional information and documents, such as:
 - Reference number of existing claim decision, if applicable
 - Patient Authorization and Notice of Release of Information
 - Appeal letter signed by the patient or authorized representative, if applicable
- Other supporting documentation, such as chart notes, current medications, test and lab results, and emergency department notes

For additional information and support, contact your Novartis Access and Reimbursement Expert or visit LEQVIOhcp.com.

References: 1. Forward Health. Denied Requests. Accessed August 7, 2025. <https://www.forwardhealth.wi.gov/WIPortal/Subsystem/KW/Print.aspx?ia=1&p=1&sa=84&s=3&c=15&nt=Denied+Requests> 2. CGS Medicare. The Appeals Process. Accessed August 7, 2025. <https://www.cgsmedicare.com/jc/redeterminations/appeals-process.html>

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



Sample letter of appeal

Letter of Appeal template

The information below can be used as a starting point for developing a letter of appeal. All blue content describes the kind of information typically required and is not intended to be included in your final letter of appeal. All pink/bracketed content needs to be filled out based on the details of each specific appeal. Be sure to review and understand specific health plan requirements for your patient. It is also important to understand each plan's submission process (online vs fax) for appeals.

[Date]
[Health plan name]
ATTN: [Department] [Patient's Name]
[Medical/Pharmacy Director Name (if available)] [Patient's plan-specific member ID]
[Health plan address] [Patient's date of birth]
[City, State, ZIP Code] [Case number]
[Dates of service]

Re: Letter of Appeal for LEQVIO® (inclisiran)

Dear [Medical/Pharmacy Director Name],

We have read and acknowledge your policy for the responsible management of drugs in the [FOR ADULT PATIENTS AGED 18+] hypercholesterolemia or familial hypercholesterolemia (HeFH) / [FOR PEDIATRIC PATIENTS AGED 12-17] familial hypercholesterolemia (HeFH/HoFH) categories. We are writing to request that you reconsider your denial of coverage for LEQVIO®. This letter is being submitted on behalf of [Patient's name] for [Product indication], associated with diagnosis code(s) [insert ICD-10 code(s)].

The reason given for the denial was [state reason from health plan's letter]. A copy of the most recent denial letter is included along with medical notes in response to the denial. After reviewing the denial letter, we continue to feel that LEQVIO 284 mg/1.5 mL is the appropriate therapy for [Patient's name]. The relevant clinical history is summarized below.

[This plan currently lists [required step edit therapies] to be attempted prior to treatment with LEQVIO. These step edit therapies are not viable for this patient. We are requesting that the step edit therapy requirement be bypassed.]

Document the patient's history, diagnosis, current condition, and symptoms; for example, confirm the patient's:

For adult patients (aged 18+):

1. Primary diagnosis of hypercholesterolemia or heterozygous familial hypercholesterolemia (HeFH) (including relevant diagnosis code[s])
2. Secondary diagnosis of (including relevant diagnosis code[s]):
 - a) Clinical ASCVD, or
 - b) Increased risk of ASCVD. Factors that increase the risk of ASCVD include type 2 diabetes mellitus, HeFH, or 10-year risk of $\geq 20\%$
3. Previous and current LDL-C-lowering treatments. Include drug names, duration of treatment(s), responses to those treatments
4. Relevant patient history regarding diet and exercise
5. Rationale and clinical support for why other treatments are not appropriate for this patient

For pediatric patients (aged 12-17):

1. Primary diagnosis of familial hypercholesterolemia including heterozygous familial hypercholesterolemia (HeFH) or homozygous familial hypercholesterolemia (HoFH) (including relevant diagnosis code[s])
2. Previous and current LDL-C-lowering treatments. Include drug names, duration of treatment(s), responses to those treatments
3. Relevant patient history regarding diet and exercise
4. Rationale and clinical support for why other treatments are not appropriate for this patient

Provide rationale for prescribing LEQVIO® (inclisiran). Rationale may include: if adverse event occurred with another treatment, or if the treatment should be avoided due to comorbidity, lack of adequate response, etc. Provide clinical support for your recommendation as to why LEQVIO is the most appropriate treatment option. This can be clinical trial data from the LEQVIO Prescribing Information.

The ordering physician is [physician name, NPI #]. The decision may be faxed to [physician fax #] or mailed to [physician business office address]. Please also send a copy of the coverage determination decision to [patient name]. If you have any further questions about this matter, please feel free to contact me at [physician phone number] or via email at [physician email]. Thank you for your time and consideration.

Sincerely,
[Physician's signature]
[Physician name] [Patient name and signature, if applicable] [Name of practice] [Phone number]

Enclosures:
[List and attach additional documents, which may include a denial letter, Letter of Medical Necessity, Prescribing Information, clinical notes/medical records, clinical studies and efficacy data, and/or clinical practice guidelines.]

This letter is provided as an example and is meant for educational purposes only. Novartis cannot guarantee insurance coverage or reimbursement. Coverage and reimbursement may vary significantly by payer, plan, patient, and setting of care. It is the sole responsibility of the health care provider to include the proper information and ensure the accuracy of all statements used in seeking coverage and reimbursement for an individual patient.

- Address the letter to the PA department or the contact person from the denial letter.
- Include patient's name, date of birth, insurance ID number, insurance group number, dates of service, and case number.
- Acknowledge the health plan's reason(s) for denial up front.
- Include relevant ICD-10 code(s).
- Include clinical support for prescribing LEQVIO®.
- Explain why each therapy was not helping the patient achieve their treatment goals and give the duration of therapy for each agent.
- Give the physician's contact information in case there are questions that need to be answered.
- If this is a second- or third-level appeal, include the original denial letter and specific medical notes in response to the denial.
- Add clinical studies and efficacy data as reference.

You can also download this resource by visiting LEQVIOhcp.com/resources.

If you have any questions about the letter of appeal, contact your Novartis Access and Reimbursement Expert.

Please 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**

INDICATION

LEQVIO[®] injection is indicated as an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C) in adults with hypercholesterolemia, adults and pediatric patients aged 12 years and older with heterozygous familial hypercholesterolemia (HeFH), and pediatric patients aged 12 years and older with homozygous familial hypercholesterolemia (HoFH).

IMPORTANT SAFETY INFORMATION

Contraindication: 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 anaphylaxis and angioedema.

Hypersensitivity Reactions: Hypersensitivity reactions, including anaphylaxis and angioedema, have been reported in patients treated with LEQVIO. Advise patients on the signs and symptoms of hypersensitivity reactions and instruct patients to seek medical attention promptly.

Adverse Reactions: Adverse reactions in clinical trials ($\geq 3\%$ of adult patients treated with LEQVIO and more frequently than placebo) were injection site reaction, arthralgia, and bronchitis. The safety profile in pediatric patients aged 12 years and older with HeFH or HoFH was consistent with adult patients with hypercholesterolemia, except for a higher frequency of headache in pediatric patients with HeFH.

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

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