



# Billing and coding guide

For questions or support, 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**

## Overview

This guide is intended to provide an overview of coding and coverage information related to LEQVIO®. Health care professionals can reference this guide, in addition to other sources of information, to determine for themselves the appropriate claims to file for LEQVIO and the related services. Novartis does not guarantee payment or coverage for any product or service.

The health care billing environment is constantly evolving to keep pace with scientific advances and financial constraints. 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 patients' payers directly for any revised or additional requirements, information, or guidance.

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. Providers should contact third-party payers for specific information on their coding, coverage, payment policies, and fee schedules.

## Basic coverage information

Billing and coding requirements for LEQVIO® will vary based on many factors, including the site of service where the drug is administered, the type of insurance the patient has, and the benefit under which LEQVIO is covered.

### Site of service

LEQVIO may be administered in physicians' offices or in hospital outpatient departments. For most payers, the site of service will affect the billing and coding requirements. This guide provides information on coverage, coding, and billing for LEQVIO when administered in physicians' offices, hospital outpatient settings, and stand-alone alternate sites of care.

### Payer type

Coverage, as defined by each payer type and benefit package, may vary depending on the site of service and the patient's status and medical history.



#### Medicare

Medicare typically covers and separately reimburses drugs provided in the physician's office as well as most drugs provided in the hospital outpatient department that are not self-administered and are provided incident to a physician service.

Coverage under Medicare Advantage can vary by plan. Providers should check with the patient's plan for specific coverage and payment information



#### Private payers

Private payers may cover LEQVIO and the medical services associated with its administration. However, there may be restrictions on coverage, such as special requirements for distribution and precertification. Private payers may also vary in the payment methods they use to reimburse the sites of service where LEQVIO is administered



#### Medicaid

Medicaid coverage and payment for LEQVIO can vary by state or by the specific managed Medicaid plan. Providers should check with the state program or plan for specific coverage information and all payer types for fee schedules

### Benefit category

Most payers cover physician-administered products such as LEQVIO under a medical benefit rather than a pharmacy benefit. In the case of Medicare, LEQVIO will typically be covered under Part B. However, private payers and Medicaid may require that physicians obtain LEQVIO through a specialty pharmacy. Specialty pharmacies may bill the payer under the medical or pharmacy benefit, depending on what that payer requires. Additionally, Medicare Advantage payers may cover LEQVIO in a similar way to private payers depending on the benefit design of the patient.

**Reference:** Tikkanen R, et al. Published June 5, 2020. Accessed April 14, 2023. <https://www.commonwealthfund.org/international-health-policy-center/countries/united-states>

# Product, dosage, and diagnosis information



<b>FDA approval date</b>	Initial: December 22, 2021 Revised: July 7, 2023
<b>Indication</b>	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).
<b>Class</b>	LEQVIO is the only entrant in the siRNA class of therapies approved to lower LDL-C.
<b>Route of administration</b>	The recommended dosage of LEQVIO, in combination with statin therapy, 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.
<b>Clinical trials</b>	Three pivotal studies were conducted and included patients with ASCVD (ORION-10 and ORION-11), those at increased risk of ASCVD (ORION-11), and those with HeFH (ORION-9).
<b>Efficacy</b>	<ul style="list-style-type: none"> <li>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%; <math>P &lt; .0001</math>) in ASCVD patients</li> <li>In the ORION-11 clinical trial on top of a maximally tolerated statin, LEQVIO demonstrated 50% LDL-C reduction vs placebo at Month 17 (95% CI: -53%, -47%; <math>P &lt; .0001</math>) in ASCVD patients and patients at increased risk of ASCVD*</li> <li>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%; <math>P &lt; .0001</math>) in patients with HeFH</li> </ul>
<b>Safety</b>	Adverse reactions in clinical trials ( $\geq 3\%$ of patients treated with LEQVIO and more frequently than placebo) were injection site reaction, arthralgia, and bronchitis.

CI, confidence interval; siRNA, small interfering ribonucleic acid; T2DM, type 2 diabetes mellitus.

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

**Reference:** Leqvio. Prescribing information. Novartis Pharmaceuticals Corp.

**Please see Important Safety Information on page 37.**  
Click [here](#) for LEQVIO full Prescribing Information.

 **LEQVIO®**  
(inclisiran) injection  
284 mg/1.5 mL

## Physician's office: relevant codes

**Disclaimer:** The site of care determines specific coding requirements. It is always the provider's responsibility to determine medical necessity for a specific service, the proper site for delivery of any services, and to submit appropriate codes, charges, and modifiers for services that are rendered.

The table below provides common procedure and drug codes that may be related to administration of LEQVIO® in the physician office setting.

### Healthcare Common Procedure Coding System (HCPCS) level II code(s)<sup>1,2</sup>

HCPCS code	Descriptor	Billing units
J1306	Injection, inclisiran, 1 mg	284

**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.

### Current Procedural Terminology (CPT) code<sup>3</sup>

CPT code*	Description
96372	Therapeutic, Prophylactic, and Diagnostic Injection (specific substance or drug; subcutaneous or intramuscular)

For a list of potentially applicable diagnosis codes, please see the [ICD-10-CM codes tab](#)

### National Drug Code (NDC)<sup>4</sup>

The National Drug Code is a unique 10-digit, 3-segment number. It is a universal product identifier for drugs in the United States present on all over-the-counter and prescription medication packages and inserts.

Many NDC numbers listed on drug packaging are in a 10-digit format. The NDC number is essential for proper claim processing when submitting claims for drugs used; however, to be recognized by payers, it must be formatted into an 11-digit 5-4-2 sequence. This requires a zero to be placed in a specific position to meet the 5-4-2 format requirement. As not all NDC numbers are set up the same, the table below demonstrates how to achieve the 11-digit NDC code for LEQVIO.

Please note, because many practice management systems automatically remove the hyphens, be sure they are excluded from submission on the claim. Check with the patient's health insurance provider to determine sequence requirements.

Tradename	Package strength	10-digit format	NDC number	11-digit format	NDC number for payer
LEQVIO	284 mg/1.5 mL single-dose prefilled syringe	4-4-2	0078-1000-60	5-4-2	00078-1000-60

\*CPT © 2023 American Medical Association. All rights reserved.

**References:** **1.** Centers for Medicare & Medicaid Services. CMS HCPCS Application Summaries and Coding Recommendations: First Quarter, 2022 HCPCS Coding Cycle. Accessed April 14, 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 14, 2023. <https://www.aapc.com/codes/cpt-codes/96372> **4.** Leqvio. Prescribing information. Novartis Pharmaceuticals Corp.


**Please see Important Safety Information on page 37.**  
Click [here](#) for LEQVIO full Prescribing Information.

 **LEQVIO**<sup>®</sup>  
(inclisiran) injection  
284 mg/1.5 mL

# Physician's office: sample CMS-1500 claim form

LEQVIO® and the associated services provided in a physician office are billed on the CMS-1500 claim form or its electronic equivalent. A sample CMS-1500 claim form for billing LEQVIO is provided below.<sup>1</sup>

The sample claim form provided below is only an example. 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. Providers should contact third-party payers for specific information on their coding, coverage, payment policies, and fee schedules.



**HEALTH INSURANCE CLAIM FORM**  
APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA ☐ ☐ PICA ☐

1. MEDICARE (Medicare) <input type="checkbox"/> MEDICAID (Medicaid) <input type="checkbox"/> TRICARE (DoD) <input type="checkbox"/> CHAMPVA (Member ID) <input type="checkbox"/> GROUP HEALTH PLAN (ID#) <input type="checkbox"/> FECA (ID#) <input type="checkbox"/> OTHER (ID#) <input type="checkbox"/>		1a. INSURED'S I.D. NUMBER (For Program in Item 1)	
2. PATIENT'S NAME (Last Name, First Name, Middle Initial)		3. PATIENT'S BIRTH DATE MM DD YY SEX M <input type="checkbox"/> F <input type="checkbox"/>	
4. INSURED'S NAME (Last Name, First Name, Middle Initial)		5. PATIENT'S ADDRESS (No., Street)	
6. PATIENT RELATIONSHIP TO INSURED Self <input type="checkbox"/> Spouse <input type="checkbox"/> Child <input type="checkbox"/> Other <input type="checkbox"/>		7. INSURED'S ADDRESS (No., Street)	
8. RESERVED FOR NUCC USE		CITY STATE ZIP CODE TELEPHONE (Include Area Code)	
9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)		10. IS PATIENT'S CONDITION RELATED TO: YES <input type="checkbox"/> NO <input type="checkbox"/>	
11. INSURED'S POLICY GROUP OR FECA NUMBER		12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.	
13. INSURED'S DATE OF BIRTH MM DD YY SEX M <input type="checkbox"/> F <input type="checkbox"/>		14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) QUAL. MM DD YY	
15. AUTO ACCIDENT? YES <input type="checkbox"/> NO <input type="checkbox"/> PLACE (State)		16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION FROM MM DD YY TO MM DD YY	
17. OTHER CLAIM ID (Designated by NUCC)		18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES FROM MM DD YY TO MM DD YY	
19. INSURANCE PLAN NAME OR PROGRAM NAME		20. OUTSIDE LAB? YES <input type="checkbox"/> NO <input type="checkbox"/> \$ CHARGES	
21. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES <input type="checkbox"/> NO <input type="checkbox"/> # yes, complete Items 9, 9a, and 9d.		22. RESUBMISSION CODE ORIGINAL REF. NO.	
23. PRIOR AUTHORIZATION NUMBER			
24. A. DATE(S) OF SERVICE From MM DD YY To MM DD YY B. PLACE OF SERVICE C. EMG D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) E. DIAGNOSIS POINTER F. \$ CHARGES G. DAYS OF UNITS H. EPST I. ID. QUAL. J. RENDERING PROVIDER ID. #			
1 N400078100060ML1.5 07 01 2022 07 01 2022 11 J1306 JZ 284 NPI			
2 07 01 2022 07 01 2022 11 96372 NPI			
3 NPI			
4 NPI			
5 NPI			
6 NPI			
25. FEDERAL TAX I.D. NUMBER SSN EIN		26. PATIENT'S ACCOUNT NO.	
27. ACCEPT ASSIGNMENT? YES <input type="checkbox"/> NO <input type="checkbox"/> (if not, state reason)		28. TOTAL CHARGE \$	
29. AMOUNT PAID \$		30. Rvd for NUCC Use	
31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)		32. SERVICE FACILITY LOCATION INFORMATION	
33. BILLING PROVIDER ID. # & PH #		34. BILLING UNIT	
SIGNED DATE		SIGNED DATE	
NUCC Instruction Manual available at: www.nucc.org		PLEASE PRINT OR TYPE APPROVED OMB-0938-1197 FORM 1500 (02-12)	

**Box 21**  
Relevant diagnosis code(s) (ICD-10-CM).

**Box 23**  
Prior authorization number, if available.

**Box 24A**  
In the non-shaded area, list the date of service. In the shaded area, give a detailed drug description. List the N4 indicator first, then the 11-digit NDC number. Third is the unit of measurement qualifier; the unit quantity is listed at the end.  
Example N400078100060ML1.5

**Box 24D**  
Enter the appropriate HCPCS code J1306 for LEQVIO use as required by the payer.<sup>2</sup> The HCPCS code must be accompanied by the JZ modifier, indicating zero drug wasted.<sup>3</sup> Include the appropriate CPT code to report the administration procedure, 96372.<sup>4</sup>

**Box 24E**  
Enter the diagnosis code reference letter (A or B) as shown in Box 21 to relate the date of service and the procedures performed to the primary diagnosis. If there is more than one diagnosis required for a procedure code, only reference one letter from Box 21.

**Box 24G**  
Include the appropriate number of billing units for LEQVIO: 284 mg=284 billing units.

**IMPORTANT INFORMATION:** The coding, coverage, and payment information contained herein is gathered from various resources, general in nature, and subject to change without notice. Third-party payment for medical products and services is affected by numerous factors. It is always the provider's responsibility to determine the appropriate health care setting and to submit true and correct claims for those products and services rendered. Providers should contact third-party payers for specific information on their coding, coverage, and payment policies. Information and materials are provided to assist health care providers, but the responsibility to determine coverage, reimbursement, and appropriate coding for a particular patient and/or procedure remains, at all times, with the provider.

**References:** 1. Centers for Medicare & Medicaid Services. Accessed April 14, 2023. <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1500.pdf> 2. Centers for Medicare & Medicaid Services. CMS HCPCS Application Summaries and Coding Recommendations: First Quarter, 2022 HCPCS Coding Cycle. Accessed April 14, 2023. <https://www.cms.gov/files/document/2022-hcpcs-application-summary-quarter-1-2022-drugs-and-biologicals.pdf> 3. 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> 4. AAPC Coder. Accessed April 14, 2023. <https://www.aapc.com/codes/cpt-codes/96372>

Please see Important Safety Information on page 37.  
Click [here](#) for LEQVIO full Prescribing Information.

**LEQVIO®**  
(inclisiran) injection  
284 mg/1.5 mL

# Claim filing checklist

Once your patient is administered LEQVIO®, a claim for reimbursement is submitted to their health insurance provider. When submitting a claim, it is a best practice to understand the payer's specific billing and coding requirements and ensure that the submitted claim is as complete as possible. You may want to reference the following general tips when filing claims for LEQVIO:

- ☐ **Use appropriate codes to report the patient's condition, the drugs the patient received, and the services you have provided**
  - ICD-10-CM code
  - NDC
  - CPT code
  - HCPCS code
  - JZ modifier
- ☐ **Attach additional information to the claim if necessary**
  - Letter of medical necessity
  - Prescribing Information
  - Patient notes
- ☐ **Review claim for accuracy, including patient identification numbers and coding**
- ☐ **File claim as soon as possible and within health plan filing time limits**
- ☐ **Reconcile claim reports promptly and thoroughly to ensure claims have been appropriately processed and paid**
- ☐ **Verify that payment amounts correspond with your public health plan allowables and your private health plan contracts**

# Coverage and coding: hospital outpatient department

## Coverage

Coverage of LEQVIO® will vary by payer. Some payers may also apply utilization restrictions for LEQVIO. For Medicare patients, LEQVIO may be covered under Medicare Part B when used for an FDA-approved indication and when medically reasonable and necessary.

## Important Information

It is always the provider's responsibility to determine the appropriate health care setting and to submit true and correct claims for actual products and services rendered. Providers should contact third-party payers for specific information on their coding, coverage, payment policies, and fee schedules.

## Coding

**Disclaimer: The site of care determines specific coding requirements. The codes detailed in this section may be applicable when LEQVIO is administered at a hospital outpatient department.**

The table below provides common procedure and drug codes that may be related to the administration of LEQVIO.

### Healthcare Common Procedure Coding System (HCPCS) level II code(s)<sup>1,2</sup>

HCPCS code	Descriptor	Billing units
J1306	Injection, inclisiran, 1 mg	284

**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.

### Current Procedural Terminology (CPT) code<sup>3</sup>

CPT code*	Description
96372	Therapeutic, Prophylactic, and Diagnostic Injection (specific substance or drug; subcutaneous or intramuscular)

\*CPT © 2023 American Medical Association. All rights reserved.

For a list of potentially applicable diagnosis codes, please see the [ICD-10-CM codes tab](#)

**References:** 1. Centers for Medicare & Medicaid Services. CMS HCPCS Application Summaries and Coding Recommendations: First Quarter, 2022 HCPCS Coding Cycle. Accessed April 14, 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 14, 2023. <https://www.aapc.com/codes/cpt-codes/96372>

 **LEQVIO®**  
(inclisiran) injection  
284 mg/1.5 mL



## Revenue codes<sup>1</sup>

Revenue code	Description
0636	Drugs requiring detailed coding
0250	General pharmacy
0500	General outpatient services
0510	General clinic services

## National Drug Code (NDC)<sup>2</sup>

The National Drug Code is a unique 10-digit, 3-segment number. It is a universal product identifier for drugs in the United States present on all over-the-counter and prescription medication packages and inserts.

Many NDC numbers listed on drug packaging are in a 10-digit format. The NDC number is essential for proper claim processing when submitting claims for drugs used; however, to be recognized by payers, it must be formatted into an 11-digit 5-4-2 sequence. This requires a zero to be placed in a specific position to meet the 5-4-2 format requirement. As not all NDC numbers are set up the same, the table below demonstrates how to achieve the 11-digit NDC code for LEQVIO®.

Please note, because many practice management systems automatically remove the hyphens, be sure they are excluded from submission on the claim.

Tradename	Package strength	10-digit format	NDC number	11-digit format	NDC number for payer
LEQVIO	284 mg/1.5 mL single-dose prefilled syringe	4-4-2	0078-1000-60	5-4-2	00078-1000-60

**References:** **1.** Noridian Healthcare Solutions. Revenue Codes. Accessed April 14, 2023. <https://med.noridianmedicare.com/web/jea/topics/claim-submission/revenue-codes> **2.** Leqvio. Prescribing information. Novartis Pharmaceuticals Corp.



# Claim filing checklist

Once your patient is administered LEQVIO®, a claim for reimbursement is submitted to their health insurance provider. When submitting a claim, it is a best practice to understand the payer's specific billing and coding requirements and ensure that the submitted claim is as complete as possible. You may want to reference the following general tips when filing claims for LEQVIO:

- ☐ **Use appropriate codes to report the patient's condition, the drugs the patient received, and the services you have provided**
  - ICD-10-CM code
  - NDC
  - CPT code
  - HCPCS code
  - JZ modifier
- ☐ **Attach additional information to the claim if necessary**
  - Letter of medical necessity
  - Prescribing Information
  - Patient notes
- ☐ **Review claim for accuracy, including patient identification numbers and coding**
- ☐ **File claim as soon as possible and within health plan filing time limits**
- ☐ **Reconcile claim reports promptly and thoroughly to ensure claims have been appropriately processed and paid**
- ☐ **Verify that payment amounts correspond with your public health plan allowables and your private health plan contracts**

# The LEQVIO® Service Center

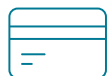
Simple, reliable, and supportive solutions to help your patients get started on LEQVIO



## ACCESS & REIMBURSEMENT SUPPORT

A dedicated Access Specialist will help with:

- Insurance verification
- PA research and appeals support
- Billing and coding questions
- Patient affordability options



## AFFORDABILITY SUPPORT

Eligible commercially insured patients **may pay as little as \$0** for LEQVIO with the co-pay savings offer.

Subject to terms and conditions. Limitations apply.\*



## ONGOING PATIENT SUPPORT

The LEQVIO Care Program will help your patients along their treatment journey with a dedicated Patient Care Specialist,<sup>†</sup> who may assist with:

- Condition and treatment information
- Patient medication reminders
- Healthy living tips and tools

To get started, download the one-page [Start Form](#).

For even more support, visit [LEQVIO-access.com](https://leqvio-access.com), or you can contact our Service Center Representatives.

**\*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.

<sup>†</sup>LEQVIO Care is a patient support program and not intended to take the place of the care provided by doctors or their office staff. LEQVIO Care does not provide medical advice or treatment.

 **LEQVIO®**  
(inclisiran) injection  
284 mg/1.5 mL

# The LEQVIO® Service Center can support 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 denied or delayed. 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.

## 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**

\*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.

# LEQVIO® distribution and acquisition

## Product Supply and NDC

LEQVIO is a sterile, clear, and colorless to pale yellow solution for subcutaneous administration supplied in a single-dose prefilled syringe.

LEQVIO is available in cartons containing 1 single-dose prefilled syringe:



284 mg/1.5 mL single-dose prefilled syringe	1 pack	10-digit NDC: 0078-1000-60 11-digit NDC: 00078-1000-60
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## Product Ordering

If you intend to buy-and-bill, LEQVIO can be ordered through our authorized distributors.

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

Novartis does not recommend the use of any particular distributor.

## Specialty Pharmacies

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**For more information on the distribution and acquisition of LEQVIO,  
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**Reference:** Leqvio. Prescribing information. Novartis Pharmaceuticals Corp.

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## Potential ICD-10-CM codes

The codes listed in this tab are provided for educational purposes only and are not a guarantee of 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 select the proper codes and ensure the accuracy of all statements used in seeking coverage and reimbursement for an individual patient.

The codes included on the following pages are included as examples of potential codes that may be relevant for LEQVIO®.

Select a link from below to view the specific codes in each category.

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#### Heterozygous familial hypercholesterolemia

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# International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) diagnosis codes

## Primary diagnosis codes

### Hyperlipidemia

ICD-10-CM diagnosis code	Description
<b>Disorders of lipoprotein metabolism and other lipidemias</b>	
E78.00	Pure hypercholesterolemia, unspecified
E78.2	Mixed hyperlipidemia
E78.4	Other hyperlipidemia
E78.49	Other hyperlipidemia, familial combined hyperlipidemia
E78.5	Hyperlipidemia, unspecified
E78.9	Disorder of lipoprotein metabolism, unspecified

### Heterozygous familial hypercholesterolemia

<b>Familial hypercholesterolemia</b>	
E78.01	Familial hypercholesterolemia
<b>Disorders of sphingolipid metabolism and other lipid storage disorders</b>	
E75.5	Other lipid storage disorders

## Secondary diagnosis codes

### Clinical ASCVD codes

<b>Atherosclerosis and atherosclerotic heart disease</b>	
I25.10	Atherosclerotic heart disease of native coronary artery without angina pectoris
I25.110	Atherosclerotic heart disease of native coronary artery with unstable angina pectoris
I25.111	Atherosclerotic heart disease of native coronary artery with angina pectoris with documented spasm
I25.118	Atherosclerotic heart disease of native coronary artery with other forms of angina pectoris
I25.119	Atherosclerotic heart disease of native coronary artery with unspecified angina pectoris

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ICD-10-CM diagnosis code	Description
I25.700	Atherosclerosis of coronary artery bypass graft(s), unspecified, with unstable angina pectoris
I25.701	Atherosclerosis of coronary artery bypass graft(s), unspecified, with angina pectoris with documented spasm
I25.708	Atherosclerosis of coronary artery bypass graft(s), unspecified, with other forms of angina pectoris
I25.709	Atherosclerosis of coronary artery bypass graft(s), unspecified, with unspecified angina pectoris
I25.710	Atherosclerosis of autologous vein coronary artery bypass graft(s) with unstable angina pectoris
I25.711	Atherosclerosis of autologous vein coronary artery bypass graft(s) with angina pectoris with documented spasm
I25.718	Atherosclerosis of autologous vein coronary artery bypass graft(s) with other forms of angina pectoris
I25.719	Atherosclerosis of autologous vein coronary artery bypass graft(s) with unspecified angina pectoris
I25.720	Atherosclerosis of autologous artery coronary artery bypass graft(s) with unstable angina pectoris
I25.721	Atherosclerosis of autologous artery coronary artery bypass graft(s) with angina pectoris with documented spasm
I25.728	Atherosclerosis of autologous artery coronary artery bypass graft(s) with other forms of angina pectoris
I25.729	Atherosclerosis of autologous artery coronary artery bypass graft(s) with unspecified angina pectoris
I25.730	Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with unstable angina pectoris
I25.731	Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with angina pectoris with documented spasm
I25.738	Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with other forms of angina pectoris
I25.739	Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with unspecified angina pectoris
I25.750	Atherosclerosis of native coronary artery of transplanted heart with unstable angina
I25.751	Atherosclerosis of native coronary artery of transplanted heart with angina pectoris with documented spasm
I25.758	Atherosclerosis of native coronary artery of transplanted heart with other forms of angina pectoris
I25.759	Atherosclerosis of native coronary artery of transplanted heart with unspecified angina pectoris
I25.760	Atherosclerosis of bypass graft of coronary artery of transplanted heart with unstable angina

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ICD-10-CM diagnosis code	Description
I25.761	Atherosclerosis of bypass graft of coronary artery of transplanted heart with angina pectoris with documented spasm
I25.768	Atherosclerosis of bypass graft of coronary artery of transplanted heart with other forms of angina pectoris
I25.769	Atherosclerosis of bypass graft of coronary artery of transplanted heart with unspecified angina pectoris
I25.790	Atherosclerosis of other coronary artery bypass graft(s) with unstable angina pectoris
I25.791	Atherosclerosis of other coronary artery bypass graft(s) with angina pectoris with documented spasm
I25.798	Atherosclerosis of other coronary artery bypass graft(s) with other forms of angina pectoris
I25.799	Atherosclerosis of other coronary artery bypass graft(s) with unspecified angina pectoris
I25.810	Atherosclerosis of coronary artery bypass graft(s) without angina pectoris
I25.811	Atherosclerosis of native coronary artery of transplanted heart without angina pectoris
I25.812	Atherosclerosis of bypass graft of coronary artery of transplanted heart without angina pectoris
<b>Ischemic heart disease (other)</b>	
I20.8	Other forms of angina pectoris
I20.9	Angina pectoris, unspecified
I23.7	Postinfarction angina
I24.0	Acute coronary thrombosis not resulting in myocardial infarction
I24.8	Other forms of acute ischemic heart disease
I25.2	Old myocardial infarction
I25.41	Coronary artery aneurysm
I25.42	Coronary artery dissection
I25.5	Ischemic cardiomyopathy
I25.6	Silent myocardial ischemia
I25.82	Chronic total occlusion of coronary artery
I25.83	Coronary atherosclerosis due to lipid rich plaque
I25.84	Coronary atherosclerosis due to calcified coronary lesion
I25.89	Other forms of chronic ischemic heart disease
I25.9	Chronic ischemic heart disease, unspecified

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ICD-10-CM diagnosis code	Description
<b>ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction</b>	
I21.01	ST elevation (STEMI) myocardial infarction involving left main coronary artery
I21.02	ST elevation (STEMI) myocardial infarction involving left anterior descending coronary artery
I21.09	ST elevation (STEMI) myocardial infarction involving other coronary artery of anterior wall
I21.11	ST elevation (STEMI) myocardial infarction involving right coronary artery
I21.19	ST elevation (STEMI) myocardial infarction involving other coronary artery of inferior wall
I21.21	ST elevation (STEMI) myocardial infarction involving left circumflex coronary artery
I21.29	ST elevation (STEMI) myocardial infarction involving other sites
I21.3	ST elevation (STEMI) myocardial infarction of unspecified site
I21.4	Non-ST elevation (NSTEMI) myocardial infarction
I22.0	Subsequent ST elevation (STEMI) myocardial infarction of anterior wall
I22.1	Subsequent ST elevation (STEMI) myocardial infarction of inferior wall
I22.2	Subsequent non-ST elevation (NSTEMI) myocardial infarction
I22.8	Subsequent ST elevation (STEMI) myocardial infarction of other sites
I22.9	Subsequent ST elevation (STEMI) myocardial infarction of unspecified site
<b>Presence of cardiac and vascular implants and grafts and other postprocedural states</b>	
Z95.1	Presence of aortocoronary bypass graft
Z95.5	Presence of coronary angioplasty implant and graft
Z98.61	Coronary angioplasty status
<b>Occlusion and stenosis of precerebral and cerebral arteries, not resulting in cerebral infarction</b>	
I65.01	Occlusion and stenosis of right vertebral artery
I65.02	Occlusion and stenosis of left vertebral artery
I65.03	Occlusion and stenosis of bilateral vertebral arteries
I65.09	Occlusion and stenosis of unspecified vertebral artery
I65.1	Occlusion and stenosis of basilar artery
I65.21	Occlusion and stenosis of right carotid artery
I65.22	Occlusion and stenosis of left carotid artery

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ICD-10-CM diagnosis code	Description
I65.23	Occlusion and stenosis of bilateral carotid arteries
I65.29	Occlusion and stenosis of unspecified carotid artery
I65.8	Occlusion and stenosis of other precerebral arteries
I65.9	Occlusion and stenosis of unspecified precerebral artery
I66.01	Occlusion and stenosis of right middle cerebral artery
I66.02	Occlusion and stenosis of left middle cerebral artery
I66.03	Occlusion and stenosis of bilateral middle cerebral arteries
I66.09	Occlusion and stenosis of unspecified middle cerebral artery
I66.11	Occlusion and stenosis of right anterior cerebral artery
I66.12	Occlusion and stenosis of left anterior cerebral artery
I66.13	Occlusion and stenosis of bilateral anterior cerebral arteries
I66.19	Occlusion and stenosis of unspecified anterior cerebral artery
I66.21	Occlusion and stenosis of right posterior cerebral artery
I66.22	Occlusion and stenosis of left posterior cerebral artery
I66.23	Occlusion and stenosis of bilateral posterior cerebral arteries
I66.29	Occlusion and stenosis of unspecified posterior cerebral artery
I66.3	Occlusion and stenosis of cerebellar arteries
I66.8	Occlusion and stenosis of other cerebral arteries
I66.9	Occlusion and stenosis of unspecified cerebral artery
<b>Cerebrovascular diseases (other)</b>	
I67.2	Cerebral atherosclerosis
I67.81	Acute cerebrovascular insufficiency
I67.82	Cerebral ischemia
I67.89	Other cerebrovascular disease
I67.9	Cerebrovascular disease, unspecified
I68.8	Other cerebrovascular disorders in diseases classified elsewhere

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ICD-10-CM diagnosis code	Description
<b>Cerebral infarction</b>	
I63.00	Cerebral infarction due to thrombosis of unspecified precerebral artery
I63.011	Cerebral infarction due to thrombosis of right vertebral artery
I63.012	Cerebral infarction due to thrombosis of left vertebral artery
I63.013	Cerebral infarction due to thrombosis of bilateral vertebral arteries
I63.019	Cerebral infarction due to thrombosis of unspecified vertebral artery
I63.02	Cerebral infarction due to thrombosis of basilar artery
I63.031	Cerebral infarction due to thrombosis of right carotid artery
I63.032	Cerebral infarction due to thrombosis of left carotid artery
I63.033	Cerebral infarction due to thrombosis of bilateral carotid arteries
I63.039	Cerebral infarction due to thrombosis of unspecified carotid artery
I63.09	Cerebral infarction due to thrombosis of other precerebral artery
I63.20	Cerebral infarction due to unspecified occlusion or stenosis of unspecified precerebral arteries
I63.211	Cerebral infarction due to unspecified occlusion or stenosis of right vertebral artery
I63.212	Cerebral infarction due to unspecified occlusion or stenosis of left vertebral artery
I63.213	Cerebral infarction due to unspecified occlusion or stenosis of bilateral vertebral arteries
I63.219	Cerebral infarction due to unspecified occlusion or stenosis of unspecified vertebral artery
I63.22	Cerebral infarction due to unspecified occlusion or stenosis of basilar arteries
I63.231	Cerebral infarction due to unspecified occlusion or stenosis of right carotid arteries
I63.232	Cerebral infarction due to unspecified occlusion or stenosis of left carotid arteries
I63.239	Cerebral infarction due to unspecified occlusion or stenosis of unspecified carotid arteries
I63.29	Cerebral infarction due to unspecified occlusion or stenosis of other precerebral arteries
I63.30	Cerebral infarction due to thrombosis of unspecified cerebral artery
I63.311	Cerebral infarction due to thrombosis of right middle cerebral artery
I63.312	Cerebral infarction due to thrombosis of left middle cerebral artery
I63.313	Cerebral infarction due to thrombosis of bilateral middle cerebral arteries

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ICD-10-CM diagnosis code	Description
I63.319	Cerebral infarction due to thrombosis of unspecified middle cerebral artery
I63.321	Cerebral infarction due to thrombosis of right anterior cerebral artery
I63.322	Cerebral infarction due to thrombosis of left anterior cerebral artery
I63.323	Cerebral infarction due to thrombosis of bilateral anterior arteries
I63.329	Cerebral infarction due to thrombosis of unspecified anterior cerebral artery
I63.331	Cerebral infarction due to thrombosis of right posterior cerebral artery
I63.332	Cerebral infarction due to thrombosis of left posterior cerebral artery
I63.333	Cerebral infarction due to thrombosis of bilateral posterior arteries
I63.339	Cerebral infarction due to thrombosis of unspecified posterior cerebral artery
I63.341	Cerebral infarction due to thrombosis of right cerebellar artery
I63.342	Cerebral infarction due to thrombosis of left cerebellar artery
I63.343	Cerebral infarction due to thrombosis of bilateral cerebellar arteries
I63.349	Cerebral infarction due to thrombosis of unspecified cerebellar artery
I63.39	Cerebral infarction due to thrombosis of other cerebral artery
I63.50	Cerebral infarction due to unspecified occlusion or stenosis of unspecified cerebral artery
I63.511	Cerebral infarction due to unspecified occlusion or stenosis of right middle cerebral artery
I63.512	Cerebral infarction due to unspecified occlusion or stenosis of left middle cerebral artery
I63.513	Cerebral infarction due to unspecified occlusion or stenosis of bilateral middle cerebral arteries
I63.519	Cerebral infarction due to unspecified occlusion or stenosis of unspecified middle cerebral artery
I63.521	Cerebral infarction due to unspecified occlusion or stenosis of right anterior cerebral artery
I63.522	Cerebral infarction due to unspecified occlusion or stenosis of left anterior cerebral artery
I63.523	Cerebral infarction due to unspecified occlusion or stenosis of bilateral anterior cerebral arteries
I63.529	Cerebral infarction due to unspecified occlusion or stenosis of unspecified anterior cerebral artery

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ICD-10-CM diagnosis code	Description
I63.531	Cerebral infarction due to unspecified occlusion or stenosis of right posterior cerebral artery
I63.532	Cerebral infarction due to unspecified occlusion or stenosis of left posterior cerebral artery
I63.533	Cerebral infarction due to unspecified occlusion or stenosis of bilateral posterior cerebral arteries
I63.539	Cerebral infarction due to unspecified occlusion or stenosis of unspecified posterior cerebral artery
I63.541	Cerebral infarction due to unspecified occlusion or stenosis of right cerebellar artery
I63.542	Cerebral infarction due to unspecified occlusion or stenosis of left cerebellar artery
I63.543	Cerebral infarction due to unspecified occlusion or stenosis of bilateral cerebellar arteries
I63.549	Cerebral infarction due to unspecified occlusion or stenosis of unspecified cerebellar artery
I63.59	Cerebral infarction due to unspecified occlusion or stenosis of other cerebral artery
I63.8	Other cerebral infarction
I63.9	Cerebral infarction, unspecified

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ICD-10-CM diagnosis code	Description
<b>Transient cerebral ischemic attack</b>	
G45.8	Other transient cerebral ischemic attacks and related syndromes
G45.9	Transient cerebral ischemic attack, unspecified
Z86.73	Personal history of transient ischemic attack (TIA), and cerebral infarction without residual deficits
<b>Vascular syndromes of brain in cerebrovascular diseases</b>	
G46.0	Middle cerebral artery syndrome
G46.1	Anterior cerebral artery syndrome
G46.2	Posterior cerebral artery syndrome
G46.3	Brain stem stroke syndrome
G46.4	Cerebellar stroke syndrome
G46.5	Pure motor lacunar syndrome
G46.6	Pure sensory lacunar syndrome
G46.7	Other lacunar syndromes
G46.8	Other vascular syndromes of brain in cerebrovascular diseases
<b>Atherosclerosis</b>	
I70.0	Atherosclerosis of aorta
I70.1	Atherosclerosis of renal artery
I70.201	Unspecified atherosclerosis of native arteries of extremities, right leg
I70.202	Unspecified atherosclerosis of native arteries of extremities, left leg
I70.203	Unspecified atherosclerosis of native arteries of extremities, bilateral legs
I70.208	Unspecified atherosclerosis of native arteries of extremities, other extremity
I70.209	Unspecified atherosclerosis of native arteries of extremities, unspecified extremity
I70.211	Atherosclerosis of native arteries of extremities with intermittent claudication, right leg
I70.212	Atherosclerosis of native arteries of extremities with intermittent claudication, left leg

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ICD-10-CM diagnosis code	Description
I70.213	Atherosclerosis of native arteries of extremities with intermittent claudication, bilateral legs
I70.218	Atherosclerosis of native arteries of extremities with intermittent claudication, other extremity
I70.219	Atherosclerosis of native arteries of extremities with intermittent claudication, unspecified extremity
I70.221	Atherosclerosis of native arteries of extremities with rest pain, right leg
I70.222	Atherosclerosis of native arteries of extremities with rest pain, left leg
I70.223	Atherosclerosis of native arteries of extremities with rest pain, bilateral legs
I70.228	Atherosclerosis of native arteries of extremities with rest pain, other extremity
I70.229	Atherosclerosis of native arteries of extremities with rest pain, unspecified extremity
I70.231	Atherosclerosis of native arteries of right leg with ulceration of thigh
I70.232	Atherosclerosis of native arteries of right leg with ulceration of calf
I70.233	Atherosclerosis of native arteries of right leg with ulceration of ankle
I70.234	Atherosclerosis of native arteries of right leg with ulceration of heel and midfoot
I70.235	Atherosclerosis of native arteries of right leg with ulceration of other part of foot
I70.238	Atherosclerosis of native arteries of right leg with ulceration of other part of lower leg
I70.239	Atherosclerosis of native arteries of right leg with ulceration of unspecified site
I70.241	Atherosclerosis of native arteries of left leg with ulceration of thigh
I70.242	Atherosclerosis of native arteries of left leg with ulceration of calf
I70.243	Atherosclerosis of native arteries of left leg with ulceration of ankle
I70.244	Atherosclerosis of native arteries of left leg with ulceration of heel and midfoot
I70.245	Atherosclerosis of native arteries of left leg with ulceration of other part of foot
I70.248	Atherosclerosis of native arteries of left leg with ulceration of other part of lower leg
I70.249	Atherosclerosis of native arteries of left leg with ulceration of unspecified site
I70.25	Atherosclerosis of native arteries of other extremities with ulceration
I70.261	Atherosclerosis of native arteries of extremities with gangrene, right leg
I70.262	Atherosclerosis of native arteries of extremities with gangrene, left leg

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ICD-10-CM diagnosis code	Description
I70.263	Atherosclerosis of native arteries of extremities with gangrene, bilateral legs
I70.268	Atherosclerosis of native arteries of extremities with gangrene, other extremity
I70.269	Atherosclerosis of native arteries of extremities with gangrene, unspecified extremity
I70.291	Other atherosclerosis of native arteries of extremities, right leg
I70.292	Other atherosclerosis of native arteries of extremities, left leg
I70.293	Other atherosclerosis of native arteries of extremities, bilateral legs
I70.298	Other atherosclerosis of native arteries of extremities, other extremity
I70.299	Other atherosclerosis of native arteries of extremities, unspecified extremity
I70.301	Unspecified atherosclerosis of unspecified type of bypass graft(s) of the extremities, right leg
I70.302	Unspecified atherosclerosis of unspecified type of bypass graft(s) of the extremities, left leg
I70.303	Unspecified atherosclerosis of unspecified type of bypass graft(s) of the extremities, bilateral legs
I70.308	Unspecified atherosclerosis of unspecified type of bypass graft(s) of the extremities, other extremity
I70.309	Unspecified atherosclerosis of unspecified type of bypass graft(s) of the extremities, unspecified extremity
I70.311	Atherosclerosis of unspecified type of bypass graft(s) of the extremities with intermittent claudication, right leg
I70.312	Atherosclerosis of unspecified type of bypass graft(s) of the extremities with intermittent claudication, left leg
I70.313	Atherosclerosis of unspecified type of bypass graft(s) of the extremities with intermittent claudication, bilateral legs
I70.318	Atherosclerosis of unspecified type of bypass graft(s) of the extremities with intermittent claudication, other extremity
I70.319	Atherosclerosis of unspecified type of bypass graft(s) of the extremities with intermittent claudication, unspecified extremity
I70.321	Atherosclerosis of unspecified type of bypass graft(s) of the extremities with rest pain, right leg
I70.322	Atherosclerosis of unspecified type of bypass graft(s) of the extremities with rest pain, left leg
I70.323	Atherosclerosis of unspecified type of bypass graft(s) of the extremities with rest pain, bilateral legs
I70.328	Atherosclerosis of unspecified type of bypass graft(s) of the extremities with rest pain, other extremity
I70.329	Atherosclerosis of unspecified type of bypass graft(s) of the extremities with rest pain, unspecified extremity

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ICD-10-CM diagnosis code	Description
I70.331	Atherosclerosis of unspecified type of bypass graft(s) of the right leg with ulceration of thigh
I70.332	Atherosclerosis of unspecified type of bypass graft(s) of the right leg with ulceration of calf
I70.333	Atherosclerosis of unspecified type of bypass graft(s) of the right leg with ulceration of ankle
I70.334	Atherosclerosis of unspecified type of bypass graft(s) of the right leg with ulceration of heel and midfoot
I70.335	Atherosclerosis of unspecified type of bypass graft(s) of the right leg with ulceration of other part of foot
I70.338	Atherosclerosis of unspecified type of bypass graft(s) of the right leg with ulceration of other part of lower leg
I70.339	Atherosclerosis of unspecified type of bypass graft(s) of the right leg with ulceration of unspecified site
I70.341	Atherosclerosis of unspecified type of bypass graft(s) of the left leg with ulceration of thigh
I70.342	Atherosclerosis of unspecified type of bypass graft(s) of the left leg with ulceration of calf
I70.343	Atherosclerosis of unspecified type of bypass graft(s) of the left leg with ulceration of ankle
I70.344	Atherosclerosis of unspecified type of bypass graft(s) of the left leg with ulceration of heel and midfoot
I70.345	Atherosclerosis of unspecified type of bypass graft(s) of the left leg with ulceration of other part of foot
I70.348	Atherosclerosis of unspecified type of bypass graft(s) of the left leg with ulceration of other part of lower leg
I70.349	Atherosclerosis of unspecified type of bypass graft(s) of the left leg with ulceration of unspecified site
I70.35	Atherosclerosis of unspecified type of bypass graft(s) of other extremity with ulceration
I70.361	Atherosclerosis of unspecified type of bypass graft(s) of the extremities with gangrene, right leg
I70.362	Atherosclerosis of unspecified type of bypass graft(s) of the extremities with gangrene, left leg
I70.363	Atherosclerosis of unspecified type of bypass graft(s) of the extremities with gangrene, bilateral legs
I70.368	Atherosclerosis of unspecified type of bypass graft(s) of the extremities with gangrene, other extremity
I70.369	Atherosclerosis of unspecified type of bypass graft(s) of the extremities with gangrene, unspecified extremity
I70.391	Other atherosclerosis of unspecified type of bypass graft(s) of the extremities, right leg
I70.392	Other atherosclerosis of unspecified type of bypass graft(s) of the extremities, left leg
I70.393	Other atherosclerosis of unspecified type of bypass graft(s) of the extremities, bilateral legs

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ICD-10-CM diagnosis code	Description
I70.398	Other atherosclerosis of unspecified type of bypass graft(s) of the extremities, other extremity
I70.399	Other atherosclerosis of unspecified type of bypass graft(s) of the extremities, unspecified extremity
I70.401	Unspecified atherosclerosis of autologous vein bypass graft(s) of the extremities, right leg
I70.402	Unspecified atherosclerosis of autologous vein bypass graft(s) of the extremities, left leg
I70.403	Unspecified atherosclerosis of autologous vein bypass graft(s) of the extremities, bilateral legs
I70.408	Unspecified atherosclerosis of autologous vein bypass graft(s) of the extremities, other extremity
I70.409	Unspecified atherosclerosis of autologous vein bypass graft(s) of the extremities, unspecified extremity
I70.411	Atherosclerosis of autologous vein bypass graft(s) of the extremities with intermittent claudication, right leg
I70.412	Atherosclerosis of autologous vein bypass graft(s) of the extremities with intermittent claudication, left leg
I70.413	Atherosclerosis of autologous vein bypass graft(s) of the extremities with intermittent claudication, bilateral legs
I70.418	Atherosclerosis of autologous vein bypass graft(s) of the extremities with intermittent claudication, other extremity
I70.419	Atherosclerosis of autologous vein bypass graft(s) of the extremities with intermittent claudication, unspecified extremity
I70.421	Atherosclerosis of autologous vein bypass graft(s) of the extremities with rest pain, right leg
I70.422	Atherosclerosis of autologous vein bypass graft(s) of the extremities with rest pain, left leg
I70.423	Atherosclerosis of autologous vein bypass graft(s) of the extremities with rest pain, bilateral legs
I70.428	Atherosclerosis of autologous vein bypass graft(s) of the extremities with rest pain, other extremity
I70.429	Atherosclerosis of autologous vein bypass graft(s) of the extremities with rest pain, unspecified extremity
I70.431	Atherosclerosis of autologous vein bypass graft(s) of the right leg with ulceration of thigh
I70.432	Atherosclerosis of autologous vein bypass graft(s) of the right leg with ulceration of calf
I70.433	Atherosclerosis of autologous vein bypass graft(s) of the right leg with ulceration of ankle
I70.434	Atherosclerosis of autologous vein bypass graft(s) of the right leg with ulceration of heel and midfoot
I70.435	Atherosclerosis of autologous vein bypass graft(s) of the right leg with ulceration of other part of foot

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ICD-10-CM diagnosis code	Description
I70.438	Atherosclerosis of autologous vein bypass graft(s) of the right leg with ulceration of other part of lower leg
I70.439	Atherosclerosis of autologous vein bypass graft(s) of the right leg with ulceration of unspecified site
I70.441	Atherosclerosis of autologous vein bypass graft(s) of the left leg with ulceration of thigh
I70.442	Atherosclerosis of autologous vein bypass graft(s) of the left leg with ulceration of calf
I70.443	Atherosclerosis of autologous vein bypass graft(s) of the left leg with ulceration of ankle
I70.444	Atherosclerosis of autologous vein bypass graft(s) of the left leg with ulceration of heel and midfoot
I70.445	Atherosclerosis of autologous vein bypass graft(s) of the left leg with ulceration of other part of foot
I70.448	Atherosclerosis of autologous vein bypass graft(s) of the left leg with ulceration of other part of lower leg
I70.449	Atherosclerosis of autologous vein bypass graft(s) of the left leg with ulceration of unspecified site
I70.45	Atherosclerosis of autologous vein bypass graft(s) of other extremity with ulceration
I70.461	Atherosclerosis of autologous vein bypass graft(s) of the extremities with gangrene, right leg
I70.462	Atherosclerosis of autologous vein bypass graft(s) of the extremities with gangrene, left leg
I70.463	Atherosclerosis of autologous vein bypass graft(s) of the extremities with gangrene, bilateral legs
I70.468	Atherosclerosis of autologous vein bypass graft(s) of the extremities with gangrene, other extremity
I70.469	Atherosclerosis of autologous vein bypass graft(s) of the extremities with gangrene, unspecified extremity
I70.491	Other atherosclerosis of autologous vein bypass graft(s) of the extremities, right leg
I70.492	Other atherosclerosis of autologous vein bypass graft(s) of the extremities, left leg
I70.493	Other atherosclerosis of autologous vein bypass graft(s) of the extremities, bilateral legs
I70.498	Other atherosclerosis of autologous vein bypass graft(s) of the extremities, other extremity
I70.499	Other atherosclerosis of autologous vein bypass graft(s) of the extremities, unspecified extremity
I70.501	Unspecified atherosclerosis of nonautologous biological bypass graft(s) of the extremities, right leg
I70.502	Unspecified atherosclerosis of nonautologous biological bypass graft(s) of the extremities, left leg

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ICD-10-CM diagnosis code	Description
I70.503	Unspecified atherosclerosis of nonautologous biological bypass graft(s) of the extremities, bilateral legs
I70.508	Unspecified atherosclerosis of nonautologous biological bypass graft(s) of the extremities, other extremity
I70.509	Unspecified atherosclerosis of nonautologous biological bypass graft(s) of the extremities, unspecified extremity
I70.511	Atherosclerosis of nonautologous biological bypass graft(s) of the extremities with intermittent claudication, right leg
I70.512	Atherosclerosis of nonautologous biological bypass graft(s) of the extremities with intermittent claudication, left leg
I70.513	Atherosclerosis of nonautologous biological bypass graft(s) of the extremities with intermittent claudication, bilateral legs
I70.518	Atherosclerosis of nonautologous biological bypass graft(s) of the extremities with intermittent claudication, other extremity
I70.519	Atherosclerosis of nonautologous biological bypass graft(s) of the extremities with intermittent claudication, unspecified extremity
I70.521	Atherosclerosis of nonautologous biological bypass graft(s) of the extremities with rest pain, right leg
I70.522	Atherosclerosis of nonautologous biological bypass graft(s) of the extremities with rest pain, left leg
I70.523	Atherosclerosis of nonautologous biological bypass graft(s) of the extremities with rest pain, bilateral legs
I70.528	Atherosclerosis of nonautologous biological bypass graft(s) of the extremities with rest pain, other extremity
I70.529	Atherosclerosis of nonautologous biological bypass graft(s) of the extremities with rest pain, unspecified extremity
I70.531	Atherosclerosis of nonautologous biological bypass graft(s) of the right leg with ulceration of thigh
I70.532	Atherosclerosis of nonautologous biological bypass graft(s) of the right leg with ulceration of calf
I70.533	Atherosclerosis of nonautologous biological bypass graft(s) of the right leg with ulceration of ankle
I70.534	Atherosclerosis of nonautologous biological bypass graft(s) of the right leg with ulceration of heel and midfoot
I70.535	Atherosclerosis of nonautologous biological bypass graft(s) of the right leg with ulceration of other part of foot
I70.538	Atherosclerosis of nonautologous biological bypass graft(s) of the right leg with ulceration of other part of lower leg
I70.539	Atherosclerosis of nonautologous biological bypass graft(s) of the right leg with ulceration of unspecified site
I70.541	Atherosclerosis of nonautologous biological bypass graft(s) of the left leg with ulceration of thigh
I70.542	Atherosclerosis of nonautologous biological bypass graft(s) of the left leg with ulceration of calf

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ICD-10-CM diagnosis code	Description
I70.543	Atherosclerosis of nonautologous biological bypass graft(s) of the left leg with ulceration of ankle
I70.544	Atherosclerosis of nonautologous biological bypass graft(s) of the left leg with ulceration of heel and midfoot
I70.545	Atherosclerosis of nonautologous biological bypass graft(s) of the left leg with ulceration of other part of foot
I70.548	Atherosclerosis of nonautologous biological bypass graft(s) of the left leg with ulceration of other part of lower leg
I70.549	Atherosclerosis of nonautologous biological bypass graft(s) of the left leg with ulceration of unspecified site
I70.55	Atherosclerosis of nonautologous biological bypass graft(s) of other extremity with ulceration
I70.561	Atherosclerosis of nonautologous biological bypass graft(s) of the extremities with gangrene, right leg
I70.562	Atherosclerosis of nonautologous biological bypass graft(s) of the extremities with gangrene, left leg
I70.563	Atherosclerosis of nonautologous biological bypass graft(s) of the extremities with gangrene, bilateral legs
I70.568	Atherosclerosis of nonautologous biological bypass graft(s) of the extremities with gangrene, other extremity
I70.569	Atherosclerosis of nonautologous biological bypass graft(s) of the extremities with gangrene, unspecified extremity
I70.591	Other atherosclerosis of nonautologous biological bypass graft(s) of the extremities, right leg
I70.592	Other atherosclerosis of nonautologous biological bypass graft(s) of the extremities, left leg
I70.593	Other atherosclerosis of nonautologous biological bypass graft(s) of the extremities, bilateral legs
I70.598	Other atherosclerosis of nonautologous biological bypass graft(s) of the extremities, other extremity
I70.599	Other atherosclerosis of nonautologous biological bypass graft(s) of the extremities, unspecified extremity
I70.601	Unspecified atherosclerosis of nonbiological bypass graft(s) of the extremities, right leg
I70.602	Unspecified atherosclerosis of nonbiological bypass graft(s) of the extremities, left leg
I70.603	Unspecified atherosclerosis of nonbiological bypass graft(s) of the extremities, bilateral legs
I70.608	Unspecified atherosclerosis of nonbiological bypass graft(s) of the extremities, other extremity
I70.609	Unspecified atherosclerosis of nonbiological bypass graft(s) of the extremities, unspecified extremity
I70.611	Atherosclerosis of nonbiological bypass graft(s) of the extremities with intermittent claudication, right leg

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ICD-10-CM diagnosis code	Description
I70.612	Atherosclerosis of nonbiological bypass graft(s) of the extremities with intermittent claudication, left leg
I70.613	Atherosclerosis of nonbiological bypass graft(s) of the extremities with intermittent claudication, bilateral legs
I70.618	Atherosclerosis of nonbiological bypass graft(s) of the extremities with intermittent claudication, other extremity
I70.619	Atherosclerosis of nonbiological bypass graft(s) of the extremities with intermittent claudication, unspecified extremity
I70.621	Atherosclerosis of nonbiological bypass graft(s) of the extremities with rest pain, right leg
I70.622	Atherosclerosis of nonbiological bypass graft(s) of the extremities with rest pain, left leg
I70.623	Atherosclerosis of nonbiological bypass graft(s) of the extremities with rest pain, bilateral legs
I70.628	Atherosclerosis of nonbiological bypass graft(s) of the extremities with rest pain, other extremity
I70.629	Atherosclerosis of nonbiological bypass graft(s) of the extremities with rest pain, unspecified extremity
I70.631	Atherosclerosis of nonbiological bypass graft(s) of the right leg with ulceration of thigh
I70.632	Atherosclerosis of nonbiological bypass graft(s) of the right leg with ulceration of calf
I70.633	Atherosclerosis of nonbiological bypass graft(s) of the right leg with ulceration of ankle
I70.634	Atherosclerosis of nonbiological bypass graft(s) of the right leg with ulceration of heel and midfoot
I70.635	Atherosclerosis of nonbiological bypass graft(s) of the right leg with ulceration of other part of foot
I70.638	Atherosclerosis of nonbiological bypass graft(s) of the right leg with ulceration of other part of lower leg
I70.639	Atherosclerosis of nonbiological bypass graft(s) of the right leg with ulceration of unspecified site
I70.641	Atherosclerosis of nonbiological bypass graft(s) of the left leg with ulceration of thigh
I70.642	Atherosclerosis of nonbiological bypass graft(s) of the left leg with ulceration of calf
I70.643	Atherosclerosis of nonbiological bypass graft(s) of the left leg with ulceration of ankle
I70.644	Atherosclerosis of nonbiological bypass graft(s) of the left leg with ulceration of heel and midfoot
I70.645	Atherosclerosis of nonbiological bypass graft(s) of the left leg with ulceration of other part of foot
I70.648	Atherosclerosis of nonbiological bypass graft(s) of the left leg with ulceration of other part of lower leg

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ICD-10-CM diagnosis code	Description
I70.649	Atherosclerosis of nonbiological bypass graft(s) of the left leg with ulceration of unspecified site
I70.65	Atherosclerosis of nonbiological bypass graft(s) of other extremity with ulceration
I70.661	Atherosclerosis of nonbiological bypass graft(s) of the extremities with gangrene, right leg
I70.662	Atherosclerosis of nonbiological bypass graft(s) of the extremities with gangrene, left leg
I70.663	Atherosclerosis of nonbiological bypass graft(s) of the extremities with gangrene, bilateral legs
I70.668	Atherosclerosis of nonbiological bypass graft(s) of the extremities with gangrene, other extremity
I70.669	Atherosclerosis of nonbiological bypass graft(s) of the extremities with gangrene, unspecified extremity
I70.691	Other atherosclerosis of nonbiological bypass graft(s) of the extremities, right leg
I70.692	Other atherosclerosis of nonbiological bypass graft(s) of the extremities, left leg
I70.693	Other atherosclerosis of nonbiological bypass graft(s) of the extremities, bilateral legs
I70.698	Other atherosclerosis of nonbiological bypass graft(s) of the extremities, other extremity
I70.699	Other atherosclerosis of nonbiological bypass graft(s) of the extremities, unspecified extremity
I70.701	Unspecified atherosclerosis of other type of bypass graft(s) of the extremities, right leg
I70.702	Unspecified atherosclerosis of other type of bypass graft(s) of the extremities, left leg
I70.703	Unspecified atherosclerosis of other type of bypass graft(s) of the extremities, bilateral legs
I70.708	Unspecified atherosclerosis of other type of bypass graft(s) of the extremities, other extremity
I70.709	Unspecified atherosclerosis of other type of bypass graft(s) of the extremities, unspecified extremity
I70.711	Atherosclerosis of other type of bypass graft(s) of the extremities with intermittent claudication, right leg
I70.712	Atherosclerosis of other type of bypass graft(s) of the extremities with intermittent claudication, left leg
I70.713	Atherosclerosis of other type of bypass graft(s) of the extremities with intermittent claudication, bilateral legs
I70.718	Atherosclerosis of other type of bypass graft(s) of the extremities with intermittent claudication, other extremity
I70.719	Atherosclerosis of other type of bypass graft(s) of the extremities with intermittent claudication, unspecified extremity

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ICD-10-CM diagnosis code	Description
I70.721	Atherosclerosis of other type of bypass graft(s) of the extremities with rest pain, right leg
I70.722	Atherosclerosis of other type of bypass graft(s) of the extremities with rest pain, left leg
I70.723	Atherosclerosis of other type of bypass graft(s) of the extremities with rest pain, bilateral legs
I70.728	Atherosclerosis of other type of bypass graft(s) of the extremities with rest pain, other extremity
I70.729	Atherosclerosis of other type of bypass graft(s) of the extremities with rest pain, unspecified extremity
I70.731	Atherosclerosis of other type of bypass graft(s) of the right leg with ulceration of thigh
I70.732	Atherosclerosis of other type of bypass graft(s) of the right leg with ulceration of calf
I70.733	Atherosclerosis of other type of bypass graft(s) of the right leg with ulceration of ankle
I70.734	Atherosclerosis of other type of bypass graft(s) of the right leg with ulceration of heel and midfoot
I70.735	Atherosclerosis of other type of bypass graft(s) of the right leg with ulceration of other part of foot
I70.738	Atherosclerosis of other type of bypass graft(s) of the right leg with ulceration of other part of lower leg
I70.739	Atherosclerosis of other type of bypass graft(s) of the right leg with ulceration of unspecified site
I70.741	Atherosclerosis of other type of bypass graft(s) of the left leg with ulceration of thigh
I70.742	Atherosclerosis of other type of bypass graft(s) of the left leg with ulceration of calf
I70.743	Atherosclerosis of other type of bypass graft(s) of the left leg with ulceration of ankle
I70.744	Atherosclerosis of other type of bypass graft(s) of the left leg with ulceration of heel and midfoot
I70.745	Atherosclerosis of other type of bypass graft(s) of the left leg with ulceration of other part of foot
I70.748	Atherosclerosis of other type of bypass graft(s) of the left leg with ulceration of other part of lower leg
I70.749	Atherosclerosis of other type of bypass graft(s) of the left leg with ulceration of unspecified site
I70.75	Atherosclerosis of other type of bypass graft(s) of other extremity with ulceration
I70.761	Atherosclerosis of other type of bypass graft(s) of the extremities with gangrene, right leg

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ICD-10-CM diagnosis code	Description
I70.762	Atherosclerosis of other type of bypass graft(s) of the extremities with gangrene, left leg
I70.763	Atherosclerosis of other type of bypass graft(s) of the extremities with gangrene, bilateral legs
I70.768	Atherosclerosis of other type of bypass graft(s) of the extremities with gangrene, other extremity
I70.769	Atherosclerosis of other type of bypass graft(s) of the extremities with gangrene, unspecified extremity
I70.791	Other atherosclerosis of other type of bypass graft(s) of the extremities, right leg
I70.792	Other atherosclerosis of other type of bypass graft(s) of the extremities, left leg
I70.793	Other atherosclerosis of other type of bypass graft(s) of the extremities, bilateral legs
I70.798	Other atherosclerosis of other type of bypass graft(s) of the extremities, other extremity
I70.799	Other atherosclerosis of other type of bypass graft(s) of the extremities, unspecified extremity
I70.8	Atherosclerosis of other arteries
I70.90	Unspecified atherosclerosis
I70.91	Generalized atherosclerosis
I70.92	Chronic total occlusion of artery of the extremities
<b>Diseases of arteries, arterioles, and capillaries (other)</b>	
I73.89	Other specified peripheral vascular diseases
I73.9	Peripheral vascular disease, unspecified
<b>Arterial embolism and thrombosis</b>	
I74.09	Other arterial embolism and thrombosis of abdominal aorta
I74.1	Embolism and thrombosis of other and unspecified parts of aorta
I74.10	Embolism and thrombosis of unspecified parts of aorta
I74.11	Embolism and thrombosis of thoracic aorta
I74.19	Embolism and thrombosis of other parts of aorta
I74.2	Embolism and thrombosis of arteries of the upper extremities
I74.3	Embolism and thrombosis of arteries of the lower extremities
I74.4	Embolism and thrombosis of arteries of extremities, unspecified

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ICD-10-CM diagnosis code	Description
<b>Atheroembolism</b>	
I75.011	Atheroembolism of right upper extremity
I75.012	Atheroembolism of left upper extremity
I75.013	Atheroembolism of bilateral upper extremities
I75.019	Atheroembolism of unspecified upper extremity
I75.02	Atheroembolism of lower extremity
I75.021	Atheroembolism of right lower extremity
I75.022	Atheroembolism of left lower extremity
I75.023	Atheroembolism of bilateral lower extremities
I75.029	Atheroembolism of unspecified lower extremity
<b>Peripheral vascular angioplasty</b>	
Z95.820	Peripheral vascular angioplasty status with implants and grafts
Z98.62	Peripheral vascular angioplasty status

Increased risk of ASCVD\*

<b>Clinical risk factors</b>	
E11	Type 2 diabetes mellitus
N18	Chronic kidney disease
I10	Essential (primary) hypertension
<p><b>Please note:</b> The 3-digit ICD-10-CM codes above 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.</p>	
<b>Family history</b>	
Z83.42	Family history of familial hypercholesterolemia

\*The factors that increase the 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.

**Reference:** Centers for Medicare and Medicaid Services. 2022 ICD-10-CM. Accessed April 14, 2023. <https://www.cms.gov/medicare/icd-10/2022-icd-10-cm>

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# 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.

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