

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. To view a sample letter of medical exception, visit [LEQVIOhcp.com/resources](https://www.leqviohcp.com/resources). The checklist is 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](https://www.leqviohcp.com/resources)
 - 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 representative or visit [LEQVIOhcp.com](https://www.leqviohcp.com).

INDICATION

LEQVIO (inclisiran) injection is indicated as an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C) in adults with hypercholesterolemia, 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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 **LEQVIO**[®]
(inclisiran) injection
284 mg/1.5 mL

 **NOVARTIS**