



LEQVIO Therapy Plan – Epic

This LEQVIO electronic health record (EHR) best practice guide provides an overview of workflows and associated configurations within Epic to support best practices for ordering and maintaining patients on LEQVIO.

For information regarding Indication and Important Safety Information, please see at the bottom of each page. For information regarding dosing, please use the link to the Prescribing Information.

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INDICATION

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

IMPORTANT SAFETY INFORMATION

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

Please see accompanying LEQVIO full Prescribing Information.

1. LEQVIO Therapy Plan Configuration

EHR Build:

Therapy Plans allow organizations to plan a patient's scheduled injections over time, including how many injections the patient needs and how often. Orders can be placed and signed in advance and released when ready to be administered.

Therapy Plans also facilitate ease of reporting capabilities via Reporting Workbench reports to track follow-up injections and upcoming due dates.

Recommended Therapy Plan Protocol: Suggested Configuration:

Therapy Plan Name: LEQVIO

LEQVIO Injection Description - 284 mg Subcutaneous (SubQ) Day 1, then 284 mg SubQ at 3 months then every 6 months thereafter

Dose 1: Initial First Dose – Cycle 1

Orders to be included in the Therapy Plan:

- Appointment Order for Injection
- LEQVIO Medication Order

Nursing Communication

Inject LEQVIO subcutaneously into the abdomen, upper arm, or thigh. Do not inject in areas of active skin disease or injury, such as sunburns, skin rashes, inflammation, or skin infections. Inspect LEQVIO visually before use. It should appear clear and colorless to pale yellow. Do not use if particulate matter or discoloration is seen.

Important information you need to know before injecting LEQVIO

- Do not use the prefilled syringe if any of the seals on the outer carton or the seal of the plastic tray are broken
- Do not remove the needle cap until you are ready to inject
- Do not use if the prefilled syringe has been dropped after removing the needle cap
- Do not try to re-use or take apart the prefilled syringe
- Refer to the complete Instructions for Use for LEQVIO for complete administration information: https://www.novartis.com/us-en/sites/novartis_us/files/leqvio.pdf

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Dose 2: 3 Months After Dose 1 – Cycle 2

Orders to be included in the therapy plan:

- Appointment Order for Injection
- LEQVIO Medication Order

Administration Instructions

Inject LEQVIO subcutaneously into the abdomen, upper arm, or thigh. Do not inject in areas of active skin disease or injury, such as sunburns, skin rashes, inflammation, or skin infections. Inspect LEQVIO visually before use. It should appear clear and colorless to pale yellow. Do not use if particulate matter or discoloration is seen.

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Dose 3: Every 6 Months Thereafter – Cycle 3

Orders to be included in the Therapy Plan:

- Appointment Order for Injection
- LEQVIO Medication Order

Administration Instructions

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IMPORTANT SAFETY INFORMATION

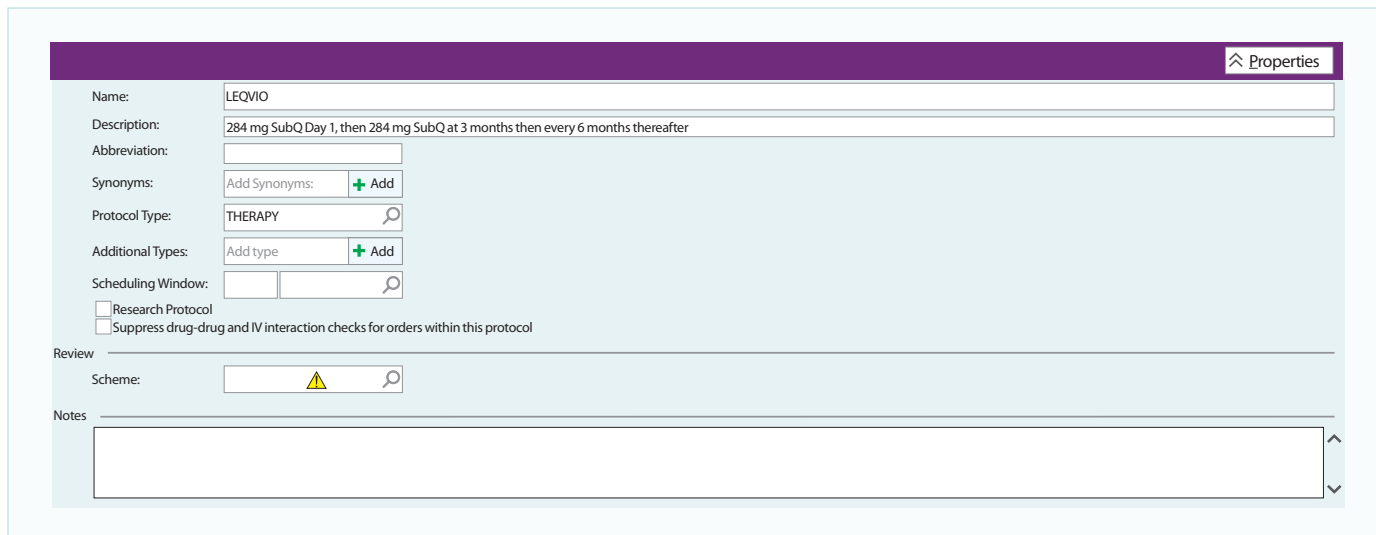
LEQVIO is contraindicated in patients with a prior serious hypersensitivity reaction to inclisiran or any of the excipients in LEQVIO. Serious hypersensitivity reactions have included angioedema. Adverse reactions in clinical trials (≥3% of patients treated with LEQVIO and more frequently than placebo)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

Please see accompanying LEQVIO full Prescribing Information.

Configuration

a. Build examples

- i. Overall Build:
 1. Open the "Therapy Protocol Builder"
 2. Create a new protocol
- ii. Edit Properties



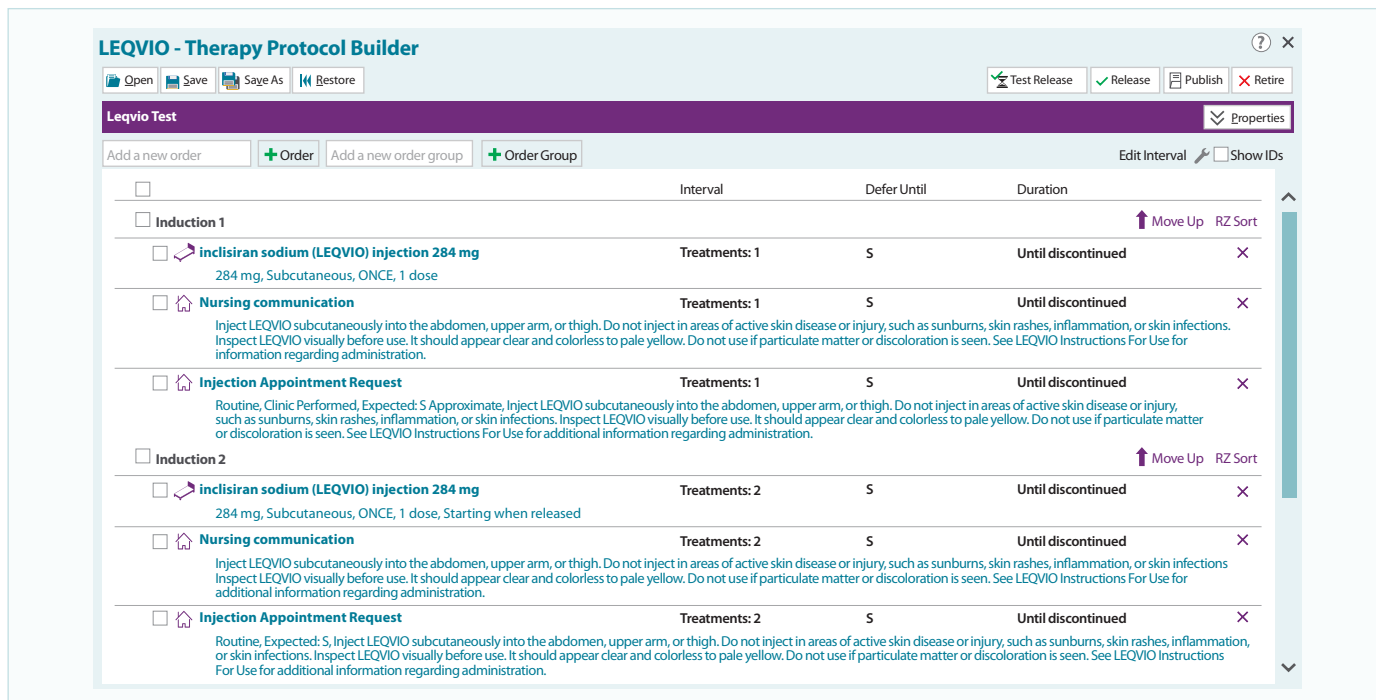
This image is intended for illustrative purposes only.

- iii. Add orders per cyclical guidance above

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LEQVIO - Therapy Protocol Builder

Open Save Save As Restore Test Release Release Publish Retire

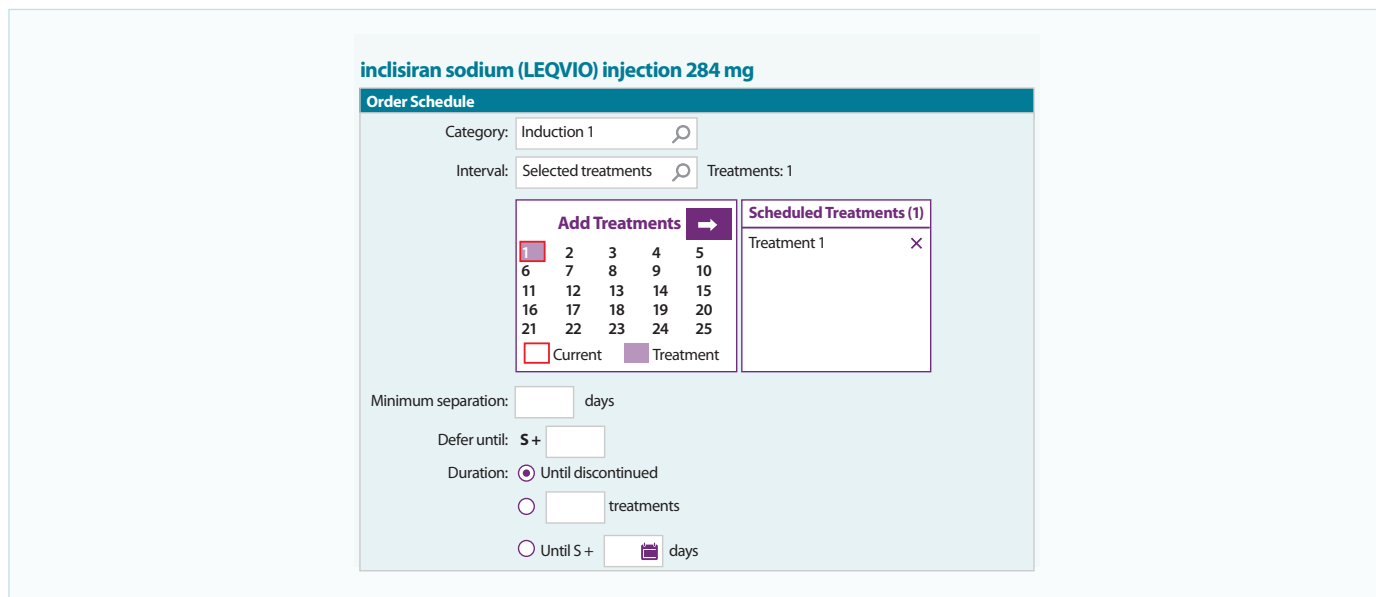
Leqvio Test Properties

Add a new order + Order Add a new order group + Order Group Edit Interval Show IDs

	Interval	Defer Until	Duration
<input type="checkbox"/> Induction 1 ↑ Move Up RZ Sort			
<input type="checkbox"/> inclisiran sodium (LEQVIO) injection 284 mg 284 mg, Subcutaneous, ONCE, 1 dose	Treatments: 1	S	Until discontinued
<input type="checkbox"/> Nursing communication Inject LEQVIO subcutaneously into the abdomen, upper arm, or thigh. Do not inject in areas of active skin disease or injury, such as sunburns, skin rashes, inflammation, or skin infections. Inspect LEQVIO visually before use. It should appear clear and colorless to pale yellow. Do not use if particulate matter or discoloration is seen. See LEQVIO Instructions For Use for information regarding administration.	Treatments: 1	S	Until discontinued
<input type="checkbox"/> Injection Appointment Request Routine, Clinic Performed, Expected: S Approximate, Inject LEQVIO subcutaneously into the abdomen, upper arm, or thigh. Do not inject in areas of active skin disease or injury, such as sunburns, skin rashes, inflammation, or skin infections. Inspect LEQVIO visually before use. It should appear clear and colorless to pale yellow. Do not use if particulate matter or discoloration is seen. See LEQVIO Instructions For Use for additional information regarding administration.	Treatments: 1	S	Until discontinued
<input type="checkbox"/> Induction 2 ↑ Move Up RZ Sort			
<input type="checkbox"/> inclisiran sodium (LEQVIO) injection 284 mg 284 mg, Subcutaneous, ONCE, 1 dose, Starting when released	Treatments: 2	S	Until discontinued
<input type="checkbox"/> Nursing communication Inject LEQVIO subcutaneously into the abdomen, upper arm, or thigh. Do not inject in areas of active skin disease or injury, such as sunburns, skin rashes, inflammation, or skin infections. Inspect LEQVIO visually before use. It should appear clear and colorless to pale yellow. Do not use if particulate matter or discoloration is seen. See LEQVIO Instructions For Use for additional information regarding administration.	Treatments: 2	S	Until discontinued
<input type="checkbox"/> Injection Appointment Request Routine, Expected: S, Inject LEQVIO subcutaneously into the abdomen, upper arm, or thigh. Do not inject in areas of active skin disease or injury, such as sunburns, skin rashes, inflammation, or skin infections. Inspect LEQVIO visually before use. It should appear clear and colorless to pale yellow. Do not use if particulate matter or discoloration is seen. See LEQVIO Instructions For Use for additional information regarding administration.	Treatments: 2	S	Until discontinued

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- iv. Ensure each order's Order Schedule groups it into the preferred cycle. If the available cycles for your organization are not what you would like, items can be added to the preference list
- v. Order Schedule Example



inclisiran sodium (LEQVIO) injection 284 mg

Order Schedule

Category: Induction 1

Interval: Selected treatments Treatments: 1

Add Treatments ➔ **Scheduled Treatments (1)**

1	2	3	4	5
6	7	8	9	10
11	12	13	14	15
16	17	18	19	20
21	22	23	24	25

☐ Current ☒ Treatment

Minimum separation: days

Defer until: S +

Duration: ☒ Until discontinued

☐ treatments

☐ Until S + days

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2. Identifying and Following Patients on LEQVIO

Leveraging Reporting Workbench is an easy way to identify patients who are actively on LEQVIO. Reports can be used to monitor progress of LDL-C reduction and identify any patients who require scheduling of future doses.

Reporting Criteria for Patients Currently on LEQVIO

- Reporting Template: Therapy Plans Generic Criteria
- Reporting Criteria:
 - i. Patient is Alive, Active Med: LEQVIO
 - ii. Reporting Columns
 - iii. Last LDL-C
 - iv. Date of last injection of LEQVIO
 - v. Date of upcoming appointment for Injection

Therapy Plan Report

1. Access Reporting Workbench
2. Search for Therapy Plan Generic Criteria report template
3. Navigate to the Criteria tab:
 - i. Which Plans? – select “Active Therapy Plans”
 - ii. Plan: Protocol – search for the LEQVIO Therapy Plan
 - iii. Plan Creator – search for the clinician who entered the Therapy Plan
 - iv. Level of Detail

Level of detail	Description
Patients	Show one row for each patient
Therapy Plans	Show one row for each therapy plan
Treatment Days	Show one row for each treatment day
Plan Orders	Show one row for each therapy plan order

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Which Plans?

Active therapy plans

Plans: Protocol

Leqvio

Level of detail

Level of Detail

1 **Therapy Plans**

Criterion Logic **OR**

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4. Navigate to the Display tab to add pertinent columns in the report, such as:

- i. Patient Name, Age, Gender
- ii. Patient MRN
- iii. Therapy Plan Name
- iv. Therapy Plan Type
- v. Therapy Plan Status
- vi. Therapy Plan Creation Date
- vii. Therapy Plan Remaining Treatments
- viii. LDL result and date columns

Available Columns

Search available columns

Problem List Matching Criteria [53267]
 Protocol ID [53222]
Protocol Name [53252]
 Requires Authorization? [53229]
 Review Due [53303]
 Review Late [53304]
 SmartData Element - Patient (EPT) [15170]
 Therapy Plan Order Active Status [53269]
Therapy Plan Order: Modified Since Last Release? [53271]

→

Selected Columns

Patient MRN [1003]
 Width (px): 77
 Patient Name, Age, and Gender [34710]
 Treatment/Therapy Plan Name [53200]
 Treatment/Therapy Plan Type [53201]
 Treatment/Therapy Plan Status [53202]
 Treatment/Therapy Plan Creation Date and Time [53254]
 Treatment/Therapy Plan Discontinuation Date and Time [53...]
 Therapy Plan Order Remaining Treatments [53270]
 Treatment/Therapy Plan ID [53216]

←

+ Add

Anchor: 0 Columns

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