LEQVIO® inclisiran

SUPPORTING SHARED CARE WITH LEQVIO® (INCLISIRAN)

Discharging your patients eligible for LEQVIO from secondary to primary care

LEQVIO is indicated in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet:
- In combination with a statin or statin with other lipid-lowering therapies in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin, or
- Alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated.[1]

This material discusses:

How to **identify patients** who are eligible for LEQVIO

How to **effectively discharge patients** to primary care for ongoing LDL-C management

An example of a discharge letter can be found on Page 3.

Identifying patients

There are multiple opportunities to identify patients who are eligible for lipid optimisation with LEQVIO in the inpatient and outpatient setting in secondary care:

1. Hospitalisations

Patient has been admitted to the hospital due to a CV event* and is **on the ward**.

LDL-C not at target† despite a maximally tolerated statin.

2. Outpatient rehab

Patient was admitted to hospital following a CV event* and is being followed up during the **rehab phase**.

LDL-C not at target† despite a maximally tolerated statin.

3. Outpatient clinic

Patient is attending a routine **outpatient appointment** post discharge. They have previously had a CV event.*

LDL-C not at target† despite a maximally tolerated statin.

These illustrative scenarios are not an exhaustive list of where eligible patients can be found.
*Events including, but not limited to, myocardial infarction, acute ischaemic stroke, TIA;
†This may vary for individual patients. Please see below for NICE-recommended criteria for LEQVIO.

Adverse Events Reporting

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard.

Adverse events should also be reported to Novartis online through the pharmacovigilance intake (PVI) tool at www.novartis.com/report or alternatively email medinfo.uk@novartis.com or call 01276 698370.

Scan or click (if viewing digitally) **the QR code to view the Prescribing Information**

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Identifying patients

In all three scenarios, first check if your patients meet the NICE-recommended criteria for LEQVIO

NICE recommends LEQVIO, within its licensed indication, as an option for the treatment of adult patients who:[2]

1 **Have already had certain CV events** (ACS such as MI or unstable angina needing hospitalisation, coronary or other arterial revascularisation procedures, CHD, ischaemic stroke or PAD).

AND

2 **Have persistently elevated LDL-C levels (≥2.6 mmol/L)** despite maximum tolerated statins with or without lipid-lowering therapies, or other lipid-lowering therapies when statins are not tolerated or are contraindicated.

Both criteria must be met.

If you can tick 'YES' to all the questions below, your patient may be eligible to start LEQVIO according to NICE TA733:[2]

1. Does your patient have a **history** of the **CV events** above? ☐ **YES**

2. Is your patient currently on a **maximally tolerated statin** or **another lipid-lowering therapy**?
The highest intensity and frequency of a statin is determined by a clinician and can vary according to patients. ☐ **YES**

3. Does your patient have **LDL-C levels currently ≥2.6 mmol/L**? ☐ **YES**

Discharging patients

Ongoing LDL-C management of patients eligible for LEQVIO may be best achieved in primary care

Prescribing LEQVIO **does not have to add to secondary care capacity challenges**.[3]
Patients prescribed LEQVIO can be **discharged to primary care** for their ongoing LDL-C management.

With straightforward, twice-yearly maintenance dosing‡ and no refrigeration required, **LEQVIO may easily fit into your patients' routine primary care appointments.**

‡In combination with a maximally tolerated statin. After an initial dose, LEQVIO is administered again at 3 months, followed by every 6 months.[1]

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Discharging patients

Your Discharge Summary can facilitate the ongoing LDL-C management of your eligible patients in primary care

This Discharge Summary is of a fictitious patient and has been created as an example only. Not to be copied for clinical use. Please see individual product SmPCs prior to prescribing.

In clinical trials, LEQVIO had a safety profile similar to placebo, apart from injection site reactions (8.2% vs 1.8%, respectively).[1]

Discharge Summary example:
Date: 11 September 2024
Patient NHS number: XXXXXX
Hospital name and address: XXXXXX

Dear Primary Care Colleague,

Preeti was admitted to hospital following a myocardial infarction on 8 August 2024.

Preeti has a history of hypercholesterolaemia and has been taking 40 mg atorvastatin for the past few years. 6 months ago, she was uptitrated to 80 mg atorvastatin but has reported severe muscle aches and fatigue. The dose was reduced back to 40 mg atorvastatin 3 months ago.

Preeti is an ex-smoker, consumes low levels of alcohol a week and exercises regularly. Her weight is 67 kg, with a BMI of 24.6. Preeti has a family history of CV disease. Her father has AF and had a TIA at the age of 56. Preeti's father also has type 2 diabetes. Her full lipid profile dated 16 August 2024 shows:

Total cholesterol = 6.56 mmol/L
LDL-C = 4.1 mmol/L
HDL-C = 1.89 mmol/L
Non-HDL = 4.67 mmol/L
Triglyceride = 1.38 mmol/L

As we are dealing with secondary prevention here, Preeti was eligible for LEQVIO injections on top of her statin. I explained to Preeti the potential LDL-C reductions that LEQVIO could provide and talked her through the side effects, with the main being injection site reactions. I then explained that the first two injections will be done in secondary care. The first dose has been given and the second is due in 3 months on 22 November 2024; and 6-monthly injections thereafter are to be given in primary care.

We will run a further full lipid profile a week before her second injection in the secondary care setting. She will be reviewed in secondary care 1 month after her second dose.
Next steps for primary care: continue dosing regimen every 6 months. Though there is no mandated lab monitoring, I suggest reviewing Preeti's lipids yearly, with the aim to reduce LDL-C to below 1.4mmol/L.

Yours sincerely,
Secondary Care Colleague

ACS=acute coronary syndrome; AF=atrial fibrillation; BMI=body mass index; CHD=coronary heart disease; CV=cardiovascular; HDL-C=high-density lipoprotein cholesterol; LDL-C=low-density lipoprotein cholesterol; MI=myocardial infarction; NICE=National Institute for Health and Care Excellence; PAD=peripheral arterial disease; SmPC=Summary of Product Characteristics; TIA=transient ischaemic attack.

1. LEQVIO® (inclisiran) Summary of Product Characteristics; **2.** NICE. Inclisiran for treating primary hypercholesterolaemia or mixed dyslipidaemia [TA733]. 6 October 2021. Available from: https://www.nice.org.uk/guidance/ta733 [Last accessed: December 2024]; **3.** NHS England. Digital. Hospital Outpatient Activity, 2023-24: Main Speciality. Available from: https://digital.nhs.uk/data-and-information/publications/statistical/hospital-outpatient-activity/2023-24 [Last accessed: December 2024].

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