NHS
Cornwall and Isles of Scilly

Primary care guidance for the prescribing and supply of Inclisiran

Contents

Overview

Inclisiran (Leqvio) is the first of a new type of cholesterol-lowering treatment to boost the liver's ability to remove LDL-cholesterol from the blood. It is given by subcutaneous injection, either on its own or alongside statins or other cholesterol-lowering drugs.

Trials are currently underway to obtain cardiovascular disease (CVD) clinical outcome data, and longer term safety data.

NICE TA733 recommends Inclisiran as an option for treating primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia as an adjunct to diet in adults.

It is recommended only if:

- there is a history of ischaemic stroke, coronary heart disease or peripheral arterial disease
- low-density lipoprotein cholesterol (LDL-C) concentrations are persistently 2.6 mmol/l or more, despite maximum tolerated lipid-lowering therapy
- the company provides Inclisiran according to the commercial arrangement

Inclisiran has been added to the Cornwall Joint Formulary as second line drugs (blue) as per the recommendation in NICE TA733 (section 3.3) and NHS England letter dated 22 September 2021.

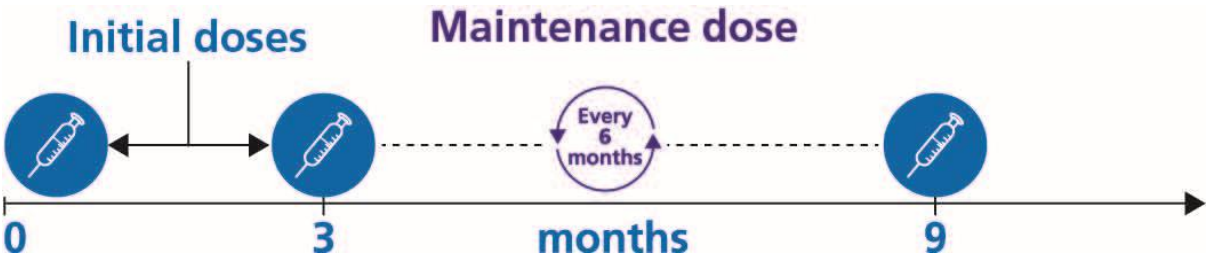
Treatment pathway

The Cornwall and Isles of Scilly Inclisiran treatment guidelines for familial or non-familial hyperlipidaemia in secondary prevention of CVD (page 3) provide detail on the decision algorithm to aid clinicians in identifying appropriate patients in whom to commence Inclisiran.

NHS Cornwall and Isles of Scilly has adopted the AAC national guidance for lipid management for primary and secondary prevention of CVD to include Inclisiran with other approved treatments:

- high intensity statins (HISTs)
- ezetimibe for use as an adjunct when statin monotherapy is ineffective, or as monotherapy for those patients that are intolerant to statins (NICE TA385)
- PCSK9 inhibitors (alirocumab, evolocumab) for use either alone or in combination with statins or ezetimibe (NICE TA393, 394)
- bempedoic acid with ezetimibe for treating primary hypercholesterolaemia or mixed dyslipidaemia as an adjunct to diet in adults (NICE TA694)

Inclisiran is administered as a subcutaneous injection into the abdomen (preferred), upper arm, or thigh. The recommended dose is 284 mg Inclisiran (pre-filled syringe) loading dose at 0 months and 3 months, then long-term maintenance every 6 months.



In case of missed doses, planned doses missed by:

- less than 3 months: administer Inclisiran and continue as per original dosing schedule
- more than 3 months: start new dosing schedule, for example initial dose, second dose at 3 months, followed by a dose every 6 months

Inclisiran is intended for administration by a healthcare professional, not the patient. No additional monitoring is required. LDL-C should be re-checked 8 weeks after the second dose.

No special storage conditions (do not freeze). Shelf-life is 3 years. For further information please refer to the SPC for Inclisiran.

Pricing structure

Inclisiran should be prescribed in primary care as a personally administered item. Practices can purchase stock from the wholesaler (AAH) by calling the customer care team on 0344 561 8899 and submit claims monthly on FP34D. Alternatively it may be prescribed on an FP10.

Practices can buy Inclisiran for £45 but the reimbursement price will be £60 if prescribed via the FP34D route. The difference between the purchase price and the NHS reimbursement price (for example £15) represents an injection administration and handling fee. Further information can be found here.

Inclisiran for the treatment of familial or non-familial hyperlipidaemia in secondary prevention of CVD

A pathway flowchart for Inclisiran in the treatment of familial or non-familial hyperlipidaemia in secondary prevention of CVD is available on the formulary.

References within the flowchart

- NHS England statin intolerance pathway
- NHS England summary of national guidance for lipid management

Prescribing information for Inclisiran (Leqvio)

Dose	Injection site	Dosing schedule	Monitoring	Missed dose
284mg single sub-cutaneous injection	Abdomen, outer thigh or upper arm.	Initial, then 3 months later, then 6 monthly thereafter.	Nil additional biochemical monitoring. LDL-C should be re-checked 8 weeks after the second dose.	If a planned dose is missed by less than 3 months, a new dosing scheduled should be started. Refer to SPC.

While discussing Inclisiran with your patients, note there are currently no outcome studies which are expected in a few years' time. In addition, as with any new medicine, the side effect profile may alter as the drug is increasingly used.

Healthcare professionals are asked to report any suspected adverse reactions via the yellow card scheme or search for MHRA yellow card in the Google Play or Apple App Store.

PCSK9i prescribing criteria

Primary prevention if the LDL-C is:

- persistently > 5 mmol/L in heterozygous familial (HF) hypercholesterolaemia

Secondary prevention if the LDL-C is:

- >4mmol/L in non-familial hypercholesterolaemia or mixed dyslipidaemia in high-risk patients (had 1 CVD event)
- >3.5mmol/L in HF hypercholesterolaemia with CVD or non-familial hypercholesterolaemia or mixed dyslipidaemia with very high-risk patients (had more than one CVD event)

If criteria met, then these patients are also eligible for PCSK9i, which therefore should be offered as an option.

Prescribing initiated and retained within secondary care by consultant chemical pathologist (lipid clinic) either Alirocumbab 75 mg subcutaneous every 2 weeks or Evolocumab 140 mg subcutaneous every 2 weeks.

Version control

Version number	Revision date	Revision by	Nature of revisions
1.0	May 2022	Marco Motta	Initial version approved by CAPC
1.1	August 2024	Chris Burgin Pharmaceutical advisor	Amended reimbursement price to £50. Link to AAC guidance updated
1.2	April 2025	Laura Trevena Pharmaceutical Advisor	Amended reimbursement price to £60. NHSE Link added regarding inclisiran access