

Inclisiran Prescribing Information Sheet

V1.2

Produced: April 23

Review date: April 24



Nottinghamshire Area Prescribing Committee

Inclisiran ▼ (Leqvio®)

Traffic light classification- Amber 3 Information sheet for Primary Care Prescribers

Indications

Inclisiran has been approved by [NICE TA733](#)¹ for the treatment of primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet, in adults (≥18 years) with:

1. History of cardiovascular disease i.e. any of the following
 - Coronary heart disease
 - Ischaemic stroke
 - Acute coronary syndrome
 - Coronary or other arterial revascularisation procedures
 - Peripheral arterial disease

AND

2. LDL-C persistently ≥ 2.6 mmol/L despite maximum tolerated lipid-lowering therapy

Inclisiran is not recommended for primary prevention except as part of research. This prescribing should not be passed out to primary care.

Therapeutic Summary

Inclisiran is a lipid lowering drug with a novel mode of action. It is a small interfering RNA (siRNA) drug, which directs the catalytic breakdown of mRNA responsible for producing the PCSK9 protein. PCSK9 directs the degradation of LDL-C receptors.

Therefore, by reducing PCSK9 production, inclisiran increases LDL-C receptor expression on the hepatocyte cell surface, which increases LDL-C uptake and thereby lowers LDL-C levels in the circulation (typically by around 50%).

Trials are currently underway to obtain CVD clinical outcome data. NICE approval was based on the assumption that the lipid lowering effect of inclisiran will result in significant CVD clinical benefits.

Medicines Initiation

Inclisiran is classified Amber 3 under the Nottinghamshire Area Prescribing Committee and will be initiated in primary care in line with the [National Guidance for Lipid Management](#)³.

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Obtaining supplies

A) Direct supply from AAH (preferred)

Inclisiran should be ordered directly to the GP practice (£45 per pre-filled syringe) by calling the AAH customer care team on 0344 561 8899 or apply for an account online <https://www.aah.co.uk/s/doctorsform>

There are no restrictions on ordering and practices do not need to evidence each individual patient with a prescription to obtain supplies. Should any problems arise please contact:

jasmin_lolita.saul@novartis.com

Inclisiran should be administered by the GP practice and added to the [FP34D/PD submission documents sent to NHS BSA](#) (done by the practice team at the end of each month).

The GP practice will be reimbursed at the NHS discounted drug tariff price of £50 (April 23). The difference between the purchase price and the NHS reimbursement price (i.e. £5) represents an injection administration and handling fee⁴.

B) FP10 prescription

An alternative route of supply is to write an FP10 to be dispensed by a pharmacy, with the patient bringing the injection to the practice to be administered.

This route of supply should be used if administration is to be done by e.g. district nursing teams in patients eligible for community nursing care.

NB: The £5 fee will not be paid if this route is used.

Products available

Inclisiran (Leqvio®) 284mg solution for injection in a pre-filled syringe

Dosages and route of administration

Inclisiran 284mg (pre-filled syringe) [administered as a subcutaneous injection](#) into the abdomen (preferred) or upper arm or thigh².

After the initial dose, inclisiran is administered again at 3 months, followed by a dose every 6 months thereafter.

No dosage adjustments are required in the elderly.

No dosage adjustment required for mild, moderate or end stage renal disease.

No dosage adjustment required in mild-moderate hepatic impairment.

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Missed doses

Planned dose missed by less than 3 months: Administer inclisiran and continue as per original dosing schedule.

Planned dose missed by more than 3 months: Start new dosing schedule i.e. initial dose, second dose at 3 months, followed by a dose every 6 months.

Reconstitution and storage (if applicable)

No special storage conditions (do not freeze). Shelf-life = 3 years.

Monitoring Requirements and Responsibilities

No specific monitoring required. LDL-C should be re-checked 8 weeks after the 2nd dose. All patients should have an annual cardiovascular disease review. Patients should be asked to report any suspected [adverse effects](#).

Explicit criteria for review and discontinuation of the medicine

Significant adverse reactions – inclisiran is a Black Triangle Drug. All ADRs should be reported via the [Yellow Card Scheme](#).

Contraindications & Precautions

Hypersensitivity to inclisiran or any of the [excipients](#).

Haemodialysis should not be performed for at least 72 hours after inclisiran dosing.

Use with caution in severe hepatic impairment (Child-Pugh class C) – no data available. Avoid in pregnancy / breastfeeding.

No data available for the use of inclisiran in children <18 years

Clinically relevant medicine interactions and their management

No known drug interactions.

Prescribing outside of licensed indication

Not applicable

Information given to patient

Inclisiran Patient Booklet – “A patient’s guide to inclisiran” may be downloaded via the following link:

<https://www.health.novartis.co.uk/sites/health.novartis.co.uk/files/inclisiran-patient-leaflet.pdf>

Other resources

Heart UK – Tackling Cholesterol Together

<https://www.heartuk.org.uk/tackling-cholesterol-together/home>
[Webinars for Health Professionals - HEART UK](#)

PrescQIPP webinar – [Lipid lowering and the role of Inclisiran](#)

Inclisiran – Frequently asked questions – for health care professionals.

<https://www.health.novartis.co.uk/sites/health.novartis.co.uk/files/inclisiran-faqs-guide.pdf>

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References

1. National Institute for Health and Care Excellence. Inclisiran for treating primary hypercholesterolaemia or mixed dyslipidaemia [Internet]. NICE;2021 (Technology Appraisal [TA733]).
2. Inclisiran 284mg solution for injection in pre filled syringe – Novartis. Summary of products characteristics [05/07/2022] on Electronic Medicines Compendium (eMC): [accessed 30/11/2022] via <http://www.medicines.org.uk>
3. Summary of National Guidance for Lipid Management for Primary and Secondary Prevention of CVD; Authors: Dr Rani Khatib & Dr Dermot Neely on behalf of the AAC Clinical Subgroup. Nov 2021. NICE endorsed Dec 2021: [accessed 30/11/2022] via <https://www.england.nhs.uk/aac/wp-content/uploads/sites/50/2020/04/National-Guidance-for-Lipid-Management-Prevention-Dec-2022.pdf>
4. NHS England. Summary information on the funding and supply of inclisiran (Leqvio®) 3 April 2023, Version 2.0 [B1913-summary-information-on-the-funding-and-supply-of-inclisiran-v-april-2023.pdf](https://www.england.nhs.uk/aac/wp-content/uploads/sites/50/2020/04/National-Guidance-for-Lipid-Management-Prevention-Dec-2022.pdf) ([england.nhs.uk](http://www.medicines.org.uk))