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].

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

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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 FP34PD submission document should be used to send all claims for personally administered items (including inclisiran). This is not referring to the FP34PD high volume appendix form (which is used for vaccines). Inclisiran administration should not be entered on this but should be counted within the FP34PD submission document. Practices must also submit an **individual FP10** for each inclisiran injection as this will trigger payment for the dispensing fee and reimbursement of the drug cost. See here for further information.

The GP practice will be reimbursed at the NHS discounted Drug Tariff price of £60 (April 25). The difference between the purchase price and the NHS reimbursement price (i.e. £15) represents an injection administration and handling fee[4].

B) FP10 prescription

An alternative route of supply is to write an FP10 to be dispensed by a community 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 £15 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) is administered as a subcutaneous injection into the abdomen (preferred) or upper arm or thigh[2].
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.

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

Patient information:
Inclisiran Patient Booklet – "A patient's guide to inclisiran" can be downloaded via:
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

NHSE Briefing note: The role of inclisiran in lipid management.
https://www.england.nhs.uk/long-read/briefing-note-the-role-of-inclisiran-in-lipid-management/#:~:text=It%20is%20usual%20practice%20for,to%20be%20safe%20and%20effective.

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 prefilled 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. March 2024. NICE endorsed March 2024: [accessed 01/04/25] via https://www.england.nhs.uk/aac/wp-content/uploads/sites/50/2020/04/lipid-management-pathway-v7.pdf
4. NHS England. Summary information on the funding and supply of inclisiran (Leqvio®) updated 31 March 2025 Summary information on the funding and supply of inclisiran (Leqvio®)