

Kent & Medway ICB Position Statement

Prescribing Inclisiran (Leqvio®) for the treatment of primary hypercholesterolaemia or mixed dyslipidaemia in Kent and Medway

May 2023

- 1) As per NICE [\[TA733\]](#) Inclisiran is recommended 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 any of the following cardiovascular events:

- acute coronary syndrome (such as myocardial infarction or unstable angina needing hospitalisation)
- coronary or other arterial revascularisation procedures
- coronary heart disease
- ischaemic stroke or
- peripheral arterial disease, **AND**

Low-density lipoprotein cholesterol (LDL-C) concentrations are persistently 2.6 mmol/l or more, despite maximum tolerated lipid-lowering therapy, that is:

- maximum tolerated statins with or without other lipid-lowering therapies or,
- other lipid-lowering therapies when statins are not tolerated or are contraindicated, and
- the company provides Inclisiran according to the commercial arrangement.

- 2) Inclisiran is able to be prescribed across Kent and Medway ICB in primary and secondary care.
- 3) Inclisiran initiation and on-going management is recommended to be carried out *predominantly within the primary care setting* where most patients with Atherosclerotic Cardiovascular Disease (ASCVD) are currently managed.
- 4) NHS England funds Inclisiran centrally from a national NHS budget ([funding and supply of inclisiran](#)) in order that local finances are not a barrier to access
- 5) *Preferred route:* Inclisiran is available in general practice as a personally administered item reimbursed via an FP10 prescription and is listed in the Drug Tariff at a Reimbursed Amount of £50 (from 01 April 2023) per injection (the £45 Nominal Charge plus £5) (note: reimbursement amount reduced from £10 to £5 from the 1st April 2023 with the introduction of the new [QOF targets \(23/24\)](#))
- 6) Inclisiran should be ordered directly from the AAH account the GP Practice has set up. To set an account with AAH the GP practice will be required to create an account by following this link: <https://www.aah.co.uk/s/opening-an-aah-account> ***

*** **IMPORTANT:** To prevent surcharges from being incurred by the practice, the practice must email AAH to state that they wish to make their account 'solus'. Once the account is marked as 'solus' no charges will be incurred.

Note: Inclisiran can also be supplied by the FP10 route, with the patient bringing the injection to the surgery for administration. If issued via FP10, patients would pay the prescription charge, if they normally do so.

The GP practice will not be paid the £5 reimbursement fee if a patient obtains Inclisiran from a pharmacy via the FP10 route.

Background

Inclisiran is the first of a new type of cholesterol-lowering treatment which uses RNA interference (RNAi) 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. The recommended dose is 284 mg Inclisiran administered as a single subcutaneous injection: initially, again at 3 months, followed by every 6 months.

Inclisiran is given by subcutaneous injection into the abdomen; alternative injection sites include the upper arm or thigh. Injections should not be given into areas of active skin disease or injury such as sunburns, skin rashes, inflammation, or skin infections.

Rationale for introduction into primary care

Inclisiran has been identified by NHS England (NHSE) as a medicine that it wishes to adopt systematically and at scale to help tackle cardiovascular disease (CVD) in a large high-risk patient population. The unique population health management (PHM) approach adopted enables systems to provide equitable access to a novel treatment and address the unmet needs of patients and health systems at an unprecedented scale in a primary care setting, where the majority of patients eligible for treatment will be identified.

The introduction of Inclisiran into the lipid management pathway addresses an unmet clinical need in which people with established CVD, despite maximum tolerated oral lipid lowering therapy, do not attain a secondary prevention LDLC target of < 1.4mmol/L and are not eligible for treatment with a PCSK9 inhibitor.

To avoid introducing unwarranted variation in access to Inclisiran a consistent approach to implementation and adoption is encouraged within the system. Collaboration with secondary care teams is recommended to ensure people who are eligible for this treatment are identified and treated in a timely manner.

Safety

Inclisiran is generally well-tolerated as demonstrated in the ORION clinical trials, with a safety profile similar to placebo apart from injection-site reactions, which were more common in the Inclisiran group.

According to the Summary of Product Characteristics, although in vitro studies were not carried out, Inclisiran is not anticipated to be a substrate for Cytochrome P450. It is not an inducer or inhibitor of P450 enzymes therefore is not expected to have clinically significant interactions with other medicinal products. For full safety information see:

https://www.ema.europa.eu/en/documents/product-information/leqvio-epar-product-information_en.pdf

Inclisiran is a black triangle drug. As with all new medicines, prescribers are advised to:

- Undertake shared decision making with patients, ensuring a full and detailed informed consent is taken, documenting the lack of long-term evidence and unknown long term safety profile of this new and novel medication,
- Encourage patients to report all side effects to their prescriber, however minor.
- Report any potential drug interactions, side effects or concerns at the earliest opportunity via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

Useful Resources & Patient identification

- The AAC/NICE National Lipid Management Pathway should be adopted to support the management of people with hypercholesterolaemia within the system
[National-Guidance-for-Lipid-Management-Prevention-Dec-2022.pdf \(england.nhs.uk\)](#)
- A systematic approach to the identification of people who will benefit from lipid optimisation is recommended; this will also identify those individuals who will benefit from novel therapies such as Inclisiran. The UCL Partners Proactive Care Frameworks for Lipid Optimisation can be used to support risk stratification and clinical prioritisation. These searches can be deployed into EMIS and are accessible via the following link:
<https://s31836.pcdn.co/wp-content/uploads/CHOLESTEROL-FINAL-V6.pdf>
- Patients eligible for Inclisiran may be identified during annual QOF or other LTC review. Alternatively, they may be identified through IT searches on:
 - Ardens
 - EMIS

It is estimated based on these searches that on average a practice will identify 2-4 eligible patients per 1000 population.

Where necessary it is recommended that potential patients are risk stratified to target those at higher risk first (more information in the link below)

- To support Primary Care with the implementation of Inclisiran, KSS AHSN have developed an Inclisiran resource pack for Primary Care and a summary Inclisiran information guide for patients that can both be downloaded from the CVD Central website here: [CVD Central – KSS AHSN](#)
The resource pack includes an example clinical pathway, operational guidance links to patient and HCP resources and answers to FAQs.

Ordering

Inclisiran initiation and management is intended to be carried out predominantly within the primary care setting where most patients with ASCVD are currently managed. However, it is possible to order in secondary care as per the guidelines below:

In Primary Care:

- The preference is for Inclisiran to be ordered directly to the GP practice (£45 per pre-filled syringe) by ordering Inclisiran directly from the AAH account the GP Practice has set up.

- **AAH Accounts:** To get set up with an account with AAH the GP practice will be required to create an account by following this link: <https://www.aah.co.uk/s/opening-an-aah-account>
- **IMPORTANT:** To prevent surcharges from being incurred by the practice, the practice must email AAH to state that they wish to make their account '**solus**'. Once the account is marked as 'solus' no charges will be incurred.
- It is recommended the best route to contact AAH is via the practice online account or by email. If necessary though the AAH customer care team are available on 0344 561 8899.

In Secondary Care:

NHS trusts can also prescribe and recharge the cost of inclisiran to NHS England which means there should not be a cost barrier to patient access to inclisiran in secondary care.

The preferred route is via an FP10HNC; prescriptions are funded from a central NHSE/I budget.

1. Eligible patients are identified by secondary care specialist in line with the NICE guidance;
2. Pre-filled syringes are ordered directly at the confidential contract price;
3. The usage is reported under Commissioned Service Category Code 21; a Blueteq form and the DrPLCM are completed and provided for reimbursement.

Stock can be ordered directly from the Novartis Customer Care Team (who can be contacted via telephone: 08457 419 442, fax: 08457 419 443 or email: commercial.team@novartis.com) using this code: EAN code 7613421044237.

It can also be supplied by FP10(HP) route (patients will need to collect the pack at a community pharmacy and get administered either at the hospital or by an appropriate primary care provider.)

Lipid management pathways for primary care and secondary care clinicians

Lipid management in England must improve to drive better CVD outcomes and, to address the clinical priority of improved lipid management, two pathways – one for acute cardiovascular disease in secondary care and one for primary care clinicians – have been developed to provide clear and simple guidance for clinicians on how optimal lipid management may be achieved and provide an additional resource to support patient management. Click the links below which take you to these two pathways.

[Pathway for secondary care – following an Acute Cardiovascular Event](#)

[Pathway for primary care – for Secondary Prevention in Primary Care](#)

The pathways provide an additional resource which can be used to support patient management. They have been developed to support healthcare professionals in implementing NICE and other relevant evidence in lipid management in secondary prevention. These are not comprehensive clinical guidelines setting out all clinical scenarios, nor do they seek to set out the clinical evidence base for interventions which is covered in the relevant NICE Technology Appraisals.

References:

- 1) NICE TA733: Inclisiran for treating primary hypercholesterolaemia or mixed dyslipidaemia:
<https://www.nice.org.uk/guidance/ta733>
- 2) Summary of Product Characteristics: Leqvio 284 mg solution for injection in prefilled syringe
<https://www.medicines.org.uk/emc/product/12039/smpc#gref>
- 3) NHSE national guidance for lipid management
[National-Guidance-for-Lipid-Management-Prevention-Dec-2022.pdf \(england.nhs.uk\)](https://www.england.nhs.uk/publication/national-guidance-for-lipid-management-prevention-dec-2022.pdf)
- 4) KSS AHSN CVD Central: Resource Pack To support Primary Care with the implementation of Inclisiran downloaded from the website: [CVD Central – KSS AHSN](#)
- 5) Quality Outcome Framework (QOF) 2023/24
<https://www.england.nhs.uk/publication/quality-and-outcomes-framework-guidance-for-2023-24/>